

# BME Design-Spring 2023 - TATUM RUBALD Complete Notebook

PDF Version generated by

**RACHEL KRUEGER**

on

May 02, 2023 @08:30 PM CDT

## Table of Contents

Project Information	2
Team contact Information	2
Project description	3
Team activities	4
Client Meetings	4
Meeting with Dr. Y - 1/25/23	4
Advisor Meetings	5
Advisor Meeting - 1/31	5
Preliminary Presentation Advisor Meeting - 02/07	6
Meeting 3/21/23	7
3/30/23 Meeting	8
Fabrication	9
STL Files	9
Testing and Results	10
Protocols	10
Testing Protocol	10
Experimentation	14
Testing Results-5/1/23	14
Project Files	16
Tong Award Paper	16
Outreach Activity	17
Preliminary Deliverables	18
Final Deliverables	19
Outreach	20
Outreach Activity Submission Files	20
Tatum Rubald	23
Research Notes	23
Biology and Physiology	23
12FEB23: Operating Room Accidents	23
3/06: Semi-Ridgid Plastics for Injection Molding	25
Design Ideas	26
12Feb23: FRIS	26
2/28: DISC Golf	29
3/3: Test Method	30
3/8: Urethane Casting for Mold Prototype	32
3/20: Casting Quote	33
3/20: Simulated Injection Molding	34
3/3: DiscGolf v2	36
Training Documentation	38
4/01/2023 Tong Lecture	38
Meeting Prep	39
16FEB2023: Goals for Team	39
Rachel Krueger	40
Research Notes	40
Competing Designs	40
4/24 Collapsible Molding	40

Design Ideas	42
2/13/2023 Labeling	42
2/13/2023 Clean Room Requirements	43
2/13/2023 Materials	44
3/5/2023 Warf Patent Review	46
3/5/2023 Injection Molding - Overhang	47
3/21/2023 Survey Questions For Testing	48
Training Documentation	50
3/31/2023 Tong Lecture	50
Victoria Heiligenthal	51
Research Notes	51
Biology and Physiology	51
Guidewire Procedure Complications - 2/23/23	51
Competing Designs	52
Failure of Complications in Medline Bowl - 2/20/23	52
Cath Clip Information-3/20/23	53
Journal Research	54
Potential Journal Options - 2/2/23	54
Journal of Medical Devices-2/21/23	55
Testing Analyzation	56
MATLAB Code	56
Running Statistics with Data-4/5/23	57
Design Ideas	58
Labeling on Packages - 2/21/23	58
Medical Grade Materials for Injection Molding-3/6/23	59
Training Documentation	60
BPAG Meeting-2/17/23	60
Make-up Tong Lecture-4/11	61
Final Poster Presentation Recording - 5/1/23	63
Benjamin Smith	64
Research Notes	64
Injection Molding	64
2/8/23 FRIS Wheel Quote	64
2/8/23 Stand Quote	67
3/5/23 Disc Golf Design Quote	70
Design Ideas	74
3/7/23 Stand	74
Lily Gallagher	76
Research Notes	76
Biology and Physiology	76
Journal Templates	76
Packaging	85
Guidewire packaging	88
Design Ideas	93
SolidWorks Drawings	93
Addison Dupies	95
Research Notes	95
2023/03/20 Warf Patent Process	95
Design Ideas	97
2022/02/13 Examples of Packaging of OR Devices	97
2022/02/08 Packaging for Class I/Class II devices	98
2014/11/03-Entry guidelines	99
2014/11/03-Template	100
Fall '22 Notebook	101



## Team contact Information

VICTORIA HEILIGENTHAL - Jan 30, 2023, 3:54 PM CST

Last Name	First Name	Role	E-mail	Phone	Office Room/Building
Surarez-Gonzalez	Darilis	Advisor			
Yamanouchi	Dai	Client			
Rubald	Tatum	Leader			
Dupies	Addie	Communicator			
Gallagher	Lily	BSAC			
Smith	Ben	BSAC			
Krueger	Rachel	BWIG			
Heiligenthal	Victoria	BPAG			



## Project description

---

John Puccinelli - Aug 14, 2013, 12:01 PM CDT

**Course Number:**

**Project Name:**

**Short Name:**

**Project description/problem statement:**

**About the client:**



## Meeting with Dr. Y - 1/25/23

---

VICTORIA HEILIGENTHAL - Jan 30, 2023, 3:05 PM CST

**Title:** Meeting with Dr. Y

**Date:** 1/25/23

**Content by:** Victoria

**Present:** All

**Goals:** To take notes on the first meeting of the semester with Dr. Y to understand goals and outline of the semester

**Content:**

- Finalize size of 3 potentially injection moldable design
- Then have price estimate
- Goal
  1. Finalize size and material
  2. Decide how far we want to go afterwards
- Testing with residents would be helpful again
  1. Potentially 3-4 people
  2. Within the next few weeks
  3. Only testing one wheel once we have a solid final wheel
- Finalize design, then find material for mass production, find price for injection molding
  1. But using 3D printing for resident testing
- End of semester will have data
- Need to know price to see if hospital, business partner or WARF could pay if too expensive
  1. WARF process if still waiting for review from patent office
  2. Dr.Y is going to ask if we can get a copy from WARF for a copy of the patent
- Our goal
  1. Completely finalizing wheel design
  2. Working with Protolabs to get a mold
  3. All Dr.Y would have to do is use the mold and print

**Conclusions/action items:** The team can decide how to move forward for the initial deliverables based on the goals from the client for this semester



## Advisor Meeting - 1/31

---

VICTORIA HEILIGENTHAL - Jan 31, 2023, 12:38 PM CST

**Title:** Advisor Meeting

**Date:** 1/31

**Content by:** Victoria

**Present:** All

**Goals:** Documenting advisor meeting

**Content:**

- Preliminary presentations
  - Forms and guidelines are generic
  - Ask client about packaging product
  - Lessons learned include throughout the entire project and last semester
    - Why we made decisions for the design moving forward
  - Budget
    - List any fees
- Journals
  - Ask client on what to move forward with this
- Goals for this semester
  - Moving forward with one design with modifications
  - Testing with cath lab techs and residents
  - Finalize design and mold to hand over to him once the semester is over
    - Want to hand over CAD model to client so easy for him
  - Patenting process is happening - checking in on status and if we can get access

**Conclusions/action items:**



## Preliminary Presentation Advisor Meeting - 02/07

---

LILY GALLAGHER - Feb 07, 2023, 1:06 PM CST

**Title:** Preliminary Presentation with Advisor

**Date:** 02/07/2023

**Content by:** Lily Gallagher

**Present:** All

**Goals:** Present our semester plans to Dr. Suarez and get feedback

**Content:**

Feedback...

- Add pictures of the comparisons of AD hold and XS hold in poster presentations
- Add “baseline” test for how the residents and cath lab techs currently, comparing our tests to that
- Feedback on criteria from Cath lab techs
- Test with stand

**Conclusions/action items:**

**Make changes to testing plans and final poster**



## Meeting 3/21/23

---

VICTORIA HEILIGENTHAL - Mar 21, 2023, 12:45 PM CDT

**Title:** Meeting 3/21/23

**Date:** 3/21/23

**Content by:** Victoria

**Present:** Everyone

**Goals:**

**Content:**

-Add authors (members and client)

-Add title

-Make document with journal and sections before next meeting to show her

-Methods: very detailed for fabrication and for testing

-Follow outlines and not just example

-Write requirements in paragraph format, not as list

-Discuss different iterations and ease into how landed into FrissV2

-Better transitions

-In intro: provide view of what designing and figure with CAD modeling (3D view of wheel and stand)

-Design requirements: add what testing is being conducted (testing 1, testing 2...) give testing names

-In results, match testing name

-Results in table for graph format, describe results as facts

**Conclusions/action items:**





## 3/30/23 Meeting

---

VICTORIA HEILIGENTHAL - Mar 30, 2023, 12:35 PM CDT

**Title:** Advisor Meeting 3/30/23

**Date:** 3/30/23

**Content by:** Victoria

**Present:** All

**Goals:**

**Content:**

- Notebook check is next week
- Can discuss testing results with her in 2 weeks, but can bring up any interesting results next week if needed
- Get competing designs in about 2 weeks for testing within the team
- Can move meetings around if need alternative time for testing
- Tong lecture is tomorrow, required for everyone
- Decide on which design award to compete for and have first draft of executive summary - Tong award makes most sense for our project
- Need to send email to her with the executive summary (get feedback from her)

**Conclusions/action items:**



---

VICTORIA HEILIGENTHAL - May 01, 2023, 3:46 PM CDT

---

VICTORIA HEILIGENTHAL - May 01, 2023, 3:47 PM CDT

**Title:** STL Files

**Date:** 5/1/23

**Content by:**

**Present:**

**Goals:**

**Content:**

See Tatum and Ben's folders for all STL files the team created for the design

**Conclusions/action items:**



# Testing Protocol

VICTORIA HEILIGENTHAL - May 01, 2023, 3:48 PM CDT

**Title:** Testing Protocol

**Date:** 5/1/23

**Content by:**

**Present:**

**Goals:**

**Content:**

## Loading

### A.1.1 Loading

Prepare test subjects by giving them an unwound GW and the wheel and instruct them that they will wind the GW and place it into the wheel. Then test subject starts trial:

*Test Subject Trial Instructions:*

(Timer is started by test admin)

1. Wind guidewire by hand into a loop
2. Pick up wheel from table
3. Use one hand to hold wheel, one to hold wire-loop
4. Slide wire-loop into wheel
5. When guidewire is fully secured within the wheel, place wheel in one hand

(Timer is stopped by test admin)

\*If the guidewire is not able to load properly, record load time as MT (mistrial)

### A.1.2 Test Admin: Grade the Load Trial (0-3)

1. The test admin watches the test subject load GW into the wheel.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to load GW
1	The GW was placed in the wheel, but there were significant issues (i.e. had to manually maneuver the GW to fit into the wheel), The wheel may be unable to dispense GW after load.
2	GW slid into the wheel with ease, but there were minor issues (i.e. the tip of the GW hung out too far, took longer to load the wheel than usual, etc.), and the wheel was ready to be dispensed.
3	GW slid into wheel without complications

### A.1.3 By User: Comfortability (1-3)

1. The user loads the GW from the wheel

2. Based on the table below, the user grades the load trial.

Comfort	Definition
1	Uncomfortable and awkward to load the GW into the wheel
2	GW is loaded with some minor issues/awkwardness and required assistance (ie: Held the wheel device wrong, could not load guidewire, did not know what to do with wheel and guidewire)
3	GW is loaded without complications and no awkwardness, high comfortability and loading with ease (ie: the wheel device was intuitive, did not need any additional assistance)

**A.1.4 Data Table**

Trial	Guidewire Specs	Load Time	Test Admin Grade	User Comfortability

**Dispensing (Solo Wheel)**

**A.2.1 Dispensing**

1. Start timer
2. Use one hand to hold wheel, and one hand to thread guidewire out of loop
3. When wire is fully out of wheel, stop timer

\*If the guidewire is not able to dispense properly, record load time as MT (mistrial)

**A.2.2 Grade the Dispense (Thread trial) (0-3)**

1. The test admin watches the test subject dispense the GW from the wheel.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to dispense GW.
1	The GW was partially removed from the wheel before tangling and popping out.
2	The GW was removed from the wheel without tangling but partially falls out of wheel during unloading
3	GW was removed from the wheel without complications.

**A.2.3 Comfortability by User (1-3)**

3. The user dispenses the GW from the wheel
4. Based on the table below, the user grades the dispense trial.

Comfort	Definition
1	Uncomfortable and awkward to dispense the GW from the wheel

2	GW is removed with some minor issues/awkwardness and required assistance (ie: Held the wheel device wrong, could not dispense guidewire, did not know what to do with wheel and guidewire)
3	GW is removed without complications and no awkwardness, high comfortability and dispensing with ease (ie: the wheel device was intuitive, did not need any additional assistance)

**A.2.4 Data Table**

Trial	Guidewire Specs	Dispense Time	Test Admin Grade	User Comfortability

**Dispensing While on Stand**

**A.3.1 Dispensing On Stand**

1. Start timer
2. Use one hand to hold stand and/or wheel, and one hand to thread guidewire out of wheel
3. When wire is fully out of wheel, stop timer

\*If the guidewire is not able to dispense properly, record load time as MT (mistrial)

**A.3.2 Grade the Stand Dispensing (Pull Trial) (0-3)**

1. The test admin watches the test subject dispense the GW from the wheel on stand.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to dispense GW.
1	The GW was removed from the wheel on stand but significant effort was needed (2 hands, extra person utilized).
2	The GW was removed from the wheel on stand but minor issues occurred (i.e. GW caught on middle chimney)
3	GW was removed from the wheel on stand without complications.

**A.3.3 Comfortability by User (1-3)**

1. The user dispenses the GW from the wheel
2. Based on the table below, the user grades the dispense trial.

Comfort	Definition
1	Uncomfortable and awkward to dispense the GW from the wheel
2	GW is removed with some minor issues/awkwardness and required assistance (ie: Could not dispense guidewire from wheel while on stand, did not know what to do with wheel, guidewire and stand)

3	GW is removed without complications and no awkwardness, high comfortability and dispensing with ease (ie: the wheel device was intuitive, did not need any additional assistance)
---	---

#### A.3.4 Data Table

Trial	Guidewire Specs	Wheel Placement	Dispense on Stand Time	Test Admin Grade	User Comfortability

Conclusions/action items:



## Testing Results-5/1/23

VICTORIA HEILIGENTHAL - May 01, 2023, 3:42 PM CDT

**Title:** Testing Results

**Date:** 5/1/23

**Content by:** Victoria

**Present:**

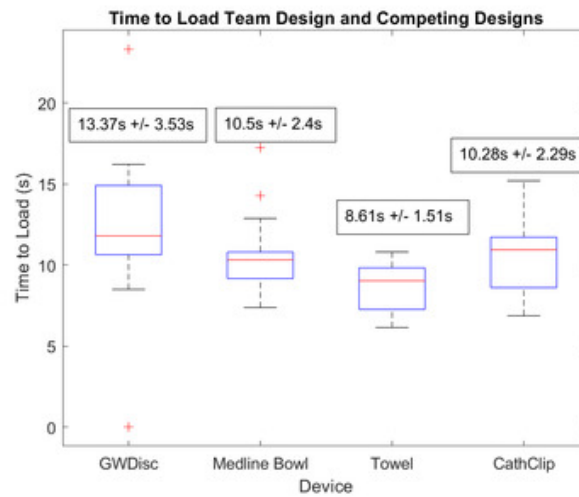
**Goals:** To document testing results from the guidewire loading of the team's design and the competing designs.

**Content:**

[https://docs.google.com/spreadsheets/d/1-OYGpoOPm9P2mYCKP0U46pg2zw9EcWJEsc6zZAuo348/edit?usp=share\\_link](https://docs.google.com/spreadsheets/d/1-OYGpoOPm9P2mYCKP0U46pg2zw9EcWJEsc6zZAuo348/edit?usp=share_link)

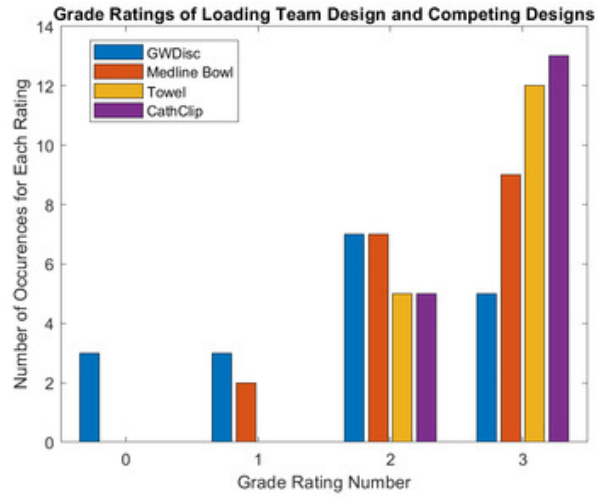
**Conclusions/action items:**

VICTORIA HEILIGENTHAL - May 01, 2023, 3:45 PM CDT



[Download](#)

402\_time\_NEW.png (41.5 kB)



[Download](#)

402\_gradeRatings.png (44 kB)





## Tong Award Paper

---

VICTORIA HEILIGENTHAL - Apr 05, 2023, 12:05 PM CDT

**Title:** Tong Award Paper

**Date:** 4/5/23

**Content by:** All

**Present:**

**Goals:**

**Content:**

<https://docs.google.com/document/d/1OZyTgFl12g8K7nU6NljQJaychWBaxV--/edit?usp=sharing&ouid=114507568317266306900&rtpof=true&sd=true>

**Conclusions/action items:**



## Outreach Activity

---

VICTORIA HEILIGENTHAL - Apr 18, 2023, 2:04 PM CDT

**Title:** Outreach Activity Materials

**Date:** 4/18/23

**Content by:** Victoria

**Present:** Victoria, Tatum, Addie, Ben, Lily

**Goals:** To document all outreach activity materials

**Content:**

Presentation: [https://docs.google.com/presentation/d/1Y04YblqTKCSiP3-RwsrOxbYa\\_udaV7LYtf8-jkV3B68/edit?usp=sharing](https://docs.google.com/presentation/d/1Y04YblqTKCSiP3-RwsrOxbYa_udaV7LYtf8-jkV3B68/edit?usp=sharing)

Activity Plan: <https://docs.google.com/document/d/1KD1rNLA3rFsf6n-yEhtOew0EpL3TOp23/edit?usp=sharing&ouid=114507568317266306900&rtopf=true&sd=true>

Class worksheet: <https://docs.google.com/document/d/15dPdHJrgCImU8szSdeWMdXe91cEGk4GaiRJQ!tZliHw/edit?usp=sharing>

**Conclusions/action items:**



## Preliminary Deliverables

---

VICTORIA HEILIGENTHAL - May 01, 2023, 12:19 PM CDT

**Title:** Preliminary Deliverables

**Date:** 5/1/23

**Content by:** Victoria

**Present:** All

**Goals:**

**Content:**

[https://docs.google.com/presentation/d/1TTn8pm9of4EnguTfRpo2IF3IXghm-g90pw7ZanLzq7Y/edit?usp=share\\_link](https://docs.google.com/presentation/d/1TTn8pm9of4EnguTfRpo2IF3IXghm-g90pw7ZanLzq7Y/edit?usp=share_link)

[https://docs.google.com/document/d/1JAQW0KGwiSK2YIP3P0Dg1X\\_Y5EiplMqYHghCdOT9xd0/edit?usp=share\\_link](https://docs.google.com/document/d/1JAQW0KGwiSK2YIP3P0Dg1X_Y5EiplMqYHghCdOT9xd0/edit?usp=share_link)

**Conclusions/action items:**



## Final Deliverables

---

VICTORIA HEILIGENTHAL - May 01, 2023, 12:19 PM CDT

**Title:** Final Deliverables

**Date:** 5/1/23

**Content by:** Victoria

**Present:** All

**Goals:**

**Content:**

<https://docs.google.com/document/d/1j8HgfviUnqWVqdxrn-N2O4WAU439VJfJJQlqxeC1dpA/edit?usp=sharing>

[https://docs.google.com/presentation/d/1Zs3FCz1t4C3cTx9i-MFmn7kBqzKc4Q5u/edit?usp=share\\_link&oid=114507568317266306900&rtpof=true&sd=true](https://docs.google.com/presentation/d/1Zs3FCz1t4C3cTx9i-MFmn7kBqzKc4Q5u/edit?usp=share_link&oid=114507568317266306900&rtpof=true&sd=true)

**Conclusions/action items:**



## Outreach Activity Submission Files

LILY GALLAGHER - May 02, 2023, 8:11 PM CDT

**Title:** Outreach Activity Submission Files

**Date:** 02MAY2023

**Content by:** Lily Gallagher

**Present:** Lily , Addison, Benjamin , Tatum, and Victoria

**Goals:** To document the outreach activity preformed by the group

**Content:**

The team conducted the outreach activity on April 21st, 2023 with Mr.Diaz's 6th grade students at Black Hawk Middle School

- The associated files are attached below

**Conclusions/action items:**

None

LILY GALLAGHER - May 02, 2023, 8:11 PM CDT

D E P A R T M E N T O F  
**Biomedical Engineering**  
College of Engineering University of Wisconsin-Madison

**Outreach Activity Plan**

Organization: University of Wisconsin-Madison Department of Biomedical Engineering

Contact person's: Addison Duques, Tatum Hubald, Lily Gallagher, Ben Smith, Victoria Heiligenthal  
Contact information: glgallag@bme.wisc.edu, tathub@bme.wisc.edu, lisa.kalsher@bme.wisc.edu, bsmith25@bme.wisc.edu, vhe@bme1@bme.wisc.edu

The team conducted the outreach activity at Black Hawk Middle School on April 21st. The students were in Mr. Diaz's 6th grade science class. There were 14 students in attendance for the activity. The class was majority boys with a few girls all between the ages of 11-13. The majority of the students were people of color. Since students were in the 6th grade, the team developed the presentation and activity in a way that was simple for the students to understand while also challenging them to learn something new.

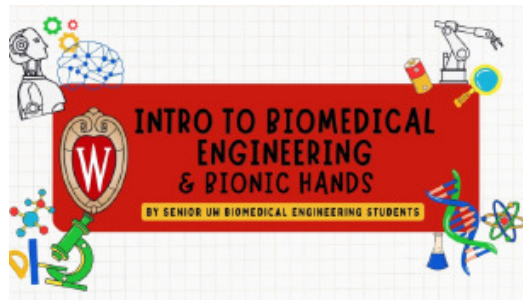
The team conducted the outreach activity during the student's last science period. The first portion of the outreach activity was an interactive presentation given by the team to teach the group about the basics of biomedical engineering. Then the hands-on activities were aimed to solve the provided problem statement involving around the medical device discussed. The first being a design project where the students were presented with a problem and must work together to fabricate a design out of the provided materials. The second being a continuation of the first design project where students were able to test the functionality of the fabricated device. In this activity, the medical device being developed was a bionic hand out of the provided materials. The only constraint the team faced was the time limit of the science class.

The activity went very well with the students. The class was engaging in the discussion and answering questions the engineering students asked to challenge them and to help them learn. The students enjoyed the activity and they all participated in creating their own bionic hand. Most students chose similar materials to fabricate their hand including scotch tape and string to represent the muscles and tendons in the hand. None of the students decided to use dental floss to represent the muscles and tendons of the hand in their design. Each student successfully designed a bionic hand that was functional during testing when they were asked to try to pick up multiple objects.

This activity could have been improved by providing more materials from students to choose from to create their hand so they had to think more about their design decisions. If more students were present, they could have paired up to create a hand so they could practice collaboration.

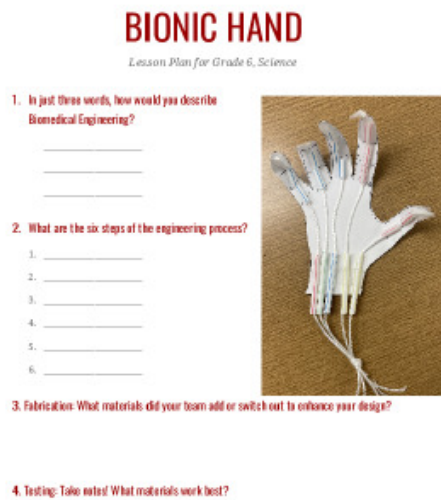
[Download](#)

**Outreach\_Overview\_Essay.pdf (47.9 kB)**



[Download](#)

**Outreach\_Presentation\_1\_.pdf (2.89 MB)**



[Download](#)

**Work\_Sheet.pdf (3.01 MB)**

D E P A R T M E N T O F  
**Biomedical Engineering**  
 College of Engineering University of Wisconsin-Madison

**Outreach Activity Plan**

Organization: University of Wisconsin-Madison Department of Biomedical Engineering

Contact person/s: Addison Dupies, Tatam Rubald, Lily Gallagher, Ben Smith, Victoria Heiligenthal  
 Contact information: [dupies@helix.edu](mailto:dupies@helix.edu), [Trubald@helix.edu](mailto:Trubald@helix.edu), [lga.gallagher@helix.edu](mailto:lga.gallagher@helix.edu),  
[bsmith75@helix.edu](mailto:bsmith75@helix.edu), [shellicent@helix.edu](mailto:shellicent@helix.edu)

**General Description**

**Type of activity**

The first portion of the outreach activity will be an interactive presentation given by five senior biomedical engineering students to teach the group about biomedical engineering, biomedical engineers, the engineering design process, and the anatomy and physiology of the hand. The students will be tasked to apply the information they learned to perform two hands-on activities to solve the provided problem statement revolving around the medical device needed. The first being a design project where they are presented with a problem and must work together to fabricate a design out of the provided materials. The medical device being developed will be a brace, hand out of the provided craft materials. The second activity will test the functionality of their device as well as evaluate mechanical advantages or disadvantages of the material used.

**Program Objectives**

**Big idea:** The objective of this project is to provide insight into the world of biomedical engineering to middle school students who are underrepresented in the STEM community. The overall theme is to give hands-on experience on designing and fabricating a prototype and then testing it for functionality. Lastly, students will learn how to make improvements on prototypes and observe what aspects of a design make it successful.

**Learning goals:**

As a result of participating in this program, visitors will be able to:

1. Explain what a biomedical engineer is and what a biomedical engineer does
2. Understand the basic concepts of the engineering design process
  - a. Learn how to apply the design concepts to the problem presented
  - b. Learn about the anatomy of the hand and physiology behind hand movements
3. Design and fabricate prototypes from design ideas
  - a. Be creative and adventurous when prototyping

1

[Download](#)

**Dupies\_Rubald\_Gallagher\_Smith-Outreach-Draft-ActivityGuide.docx\_1\_.pdf (209 kB)**



## 12FEB23: Operating Room Accidents

TATUM RUBALD - Feb 12, 2023, 1:57 PM CST

### Title: Operating Room Accidents

Date: 12FEB23

Content by: Tatum Rubald

### Goals:

I want to search literature for operating room accidents that involve tangling of guide wires.

### Content:

**A. C. Antonacci, S. Lam, V. Lavarias, P. Homel, and R. D. Eavey, "Benchmarking Surgical Incident Reports Using a Database and a Triage System to Reduce Adverse Outcomes," *Archives of Surgery*, vol. 143, no. 12, pp. 1192–1197, Dec. 2008, doi: [10.1001/archsurg.143.12.1192](https://doi.org/10.1001/archsurg.143.12.1192).**

- Hemorrhage 27.8%
- Wound and infectious complications requiring reexploration 24.3%
- Technical difficulties or errors 19.3%
- Device-related failure or mishap 13.3%
  - Exploration for retained foreign bodies composed 10% of this category

*There was no definition for technical difficulties nor device-related failure. The tangling of guidewires could fall into either of these categories, but was not specifically stated.*

**P. M. Joshi, S. R. Shivde, and T. A. Dighe, "Knotting of the guide wires: A rare complication during minimally invasive procedure on kidney-Lessons learnt," *J Minim Access Surg*, vol. 4, no. 4, pp. 114–116, 2008.**

- Flexible guide wires have lesser complication rate of tissue injury as compared to stiff guide wires
  - Flexible guide wires are however more prone to bending and kinking due to their mechanical properties
  - Unusual complication of knotting of flexible guide wires during endourologic procedure
- Buckling, kinking, and knotting is seen more commonly with flexible tip guide wires as compared to stiff guide wires.
- The stiff guide wires have more potential for causing complications such as submucosal undermining and perforation.
- 

two factors could be responsible for knotting of the guide wires:

- Excessive length of the guide wires inserted inside a small closed space such as the pelvicalyceal system.
- The force gets transferred on to the coaxial guide wire during the insertion of nephroscope in to the Amplatz sheath. This action done repeatedly causes the coaxial wire to buckle and kink.[5] Excessive torsional force created on the access wire causes such a wire to get entangled with the stable safety guide wire.

*This case study was about the tangling of a guidewire inside the body. However, the anticipated cause of the knotting could be of interest: excessive length of guidewire. The device we have created could be utilized to essentially shorten the GW by not pulling all of it out at once.*

### Conclusions/action items:

The relevance of these articles will be discussed with the team. Should also consult Dr. Suarez on her opinion.







## 3/06: Semi-Rigid Plastics for Injection Molding

---

TATUM RUBALD - Mar 08, 2023, 3:31 PM CST

### Title: Injection Molding: Tolerances and Mold

Date: 3/6

Content by: Tatum Rubald

### Goals:

I want to fully understand what is needed of the mold and the design prior to the meeting with protolabs.

### Content:

- to minimize the potential for warping and part misalignment, design should ensure it is adhering to DFM principles
- DFM principles: designing parts with the specific method of manufacturing in mind
- Maintaining uniform wall thickness throughout is key to preventing uneven shrink rates
  - can lead to deformities that inhibit the part's ability to hold tight tolerances
  - design features like support ribs are more efficient and effective in providing strength than increasing wall thickness
- Draft angles: slight taper applied to part surfaces aligned with the direction of pull are essential for ensuring that the component ejects easily
  - 1.5-2 degrees of draft is usually safe
- Tolerance of injection-molded parts can be significantly impacted by material
- plastic resins for injection molding differ based on additives, fillers, and stabilizers
  - different resins have different shrink rates
- Mold designs are typically designed to be slightly oversized-- to account for material shrinkage
- Mold tooling needs to provide consistent, repeatable heating and cooling between shots

[1 "Injection Molding Tolerances: Best Practices | Resources," *Fast Radius*. <https://www.fastradius.com/resources/injection-molding-tolerances-best-practices/> (accessed Mar. 07, 2023).

### Conclusions/action items:

DISCGOLF has uneven wall thicknesses so this idea must be modified. I am unsure how to add tolerances into Solidworks, so I need to do some research on that. This was good prep for the meeting tomorrow, however.



## 12Feb23: FRIS

---

LILY GALLAGHER - Apr 24, 2023, 8:16 PM CDT

**Title:** FRIS

**Date:** 12FEB23

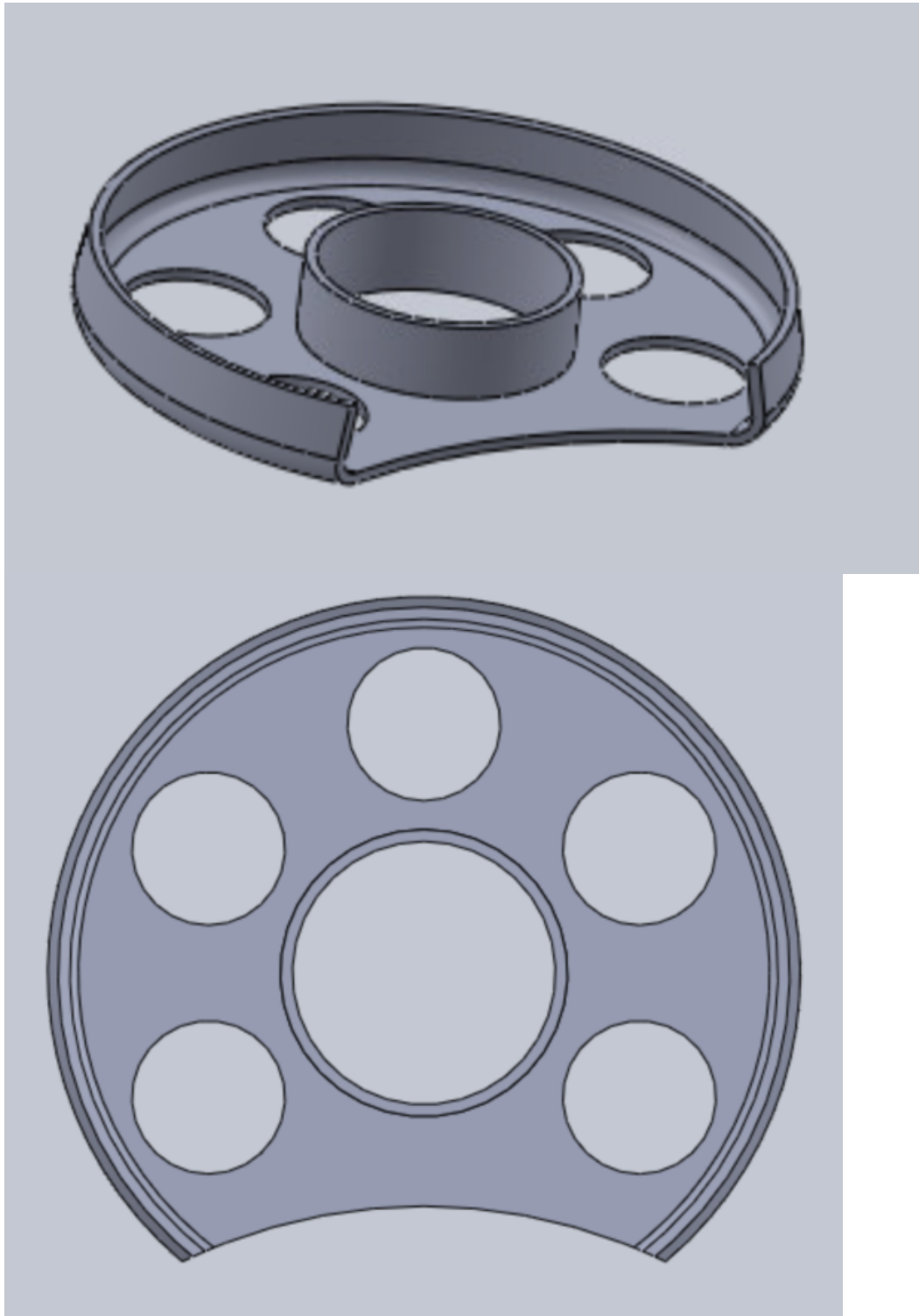
**Content by:** Tatum Rubald

**Goals:**

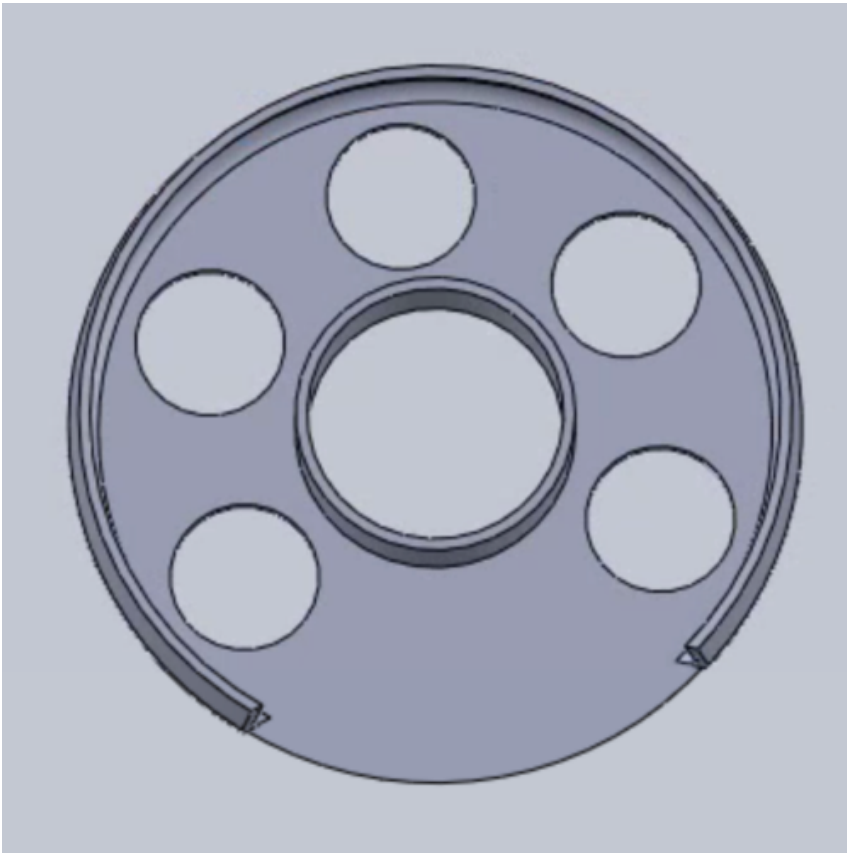
I want to make the final design of the wheel based off of the dimensions of XSHold and the design of ADHold.

**Content:**

FRISv1



FRISv2



OD: 154mm

Chimney OD: 60mm

Height: 17mm

Thickness: 2.5 mm

- FRIS v1 and v2 only differ slightly
  - v2 has the full bottom portion of the wheel
  - v1 has a semicircle cut out
- I imagine that the full bottom (v2) will help with wheel loading

**Conclusions/action items:**

Test both designs with residents in the coming weeks.

## 2/28: DISC Golf

---

TATUM RUBALD - Mar 08, 2023, 3:26 PM CST

**Title:** Disc Golf

**Date:** 2/28

**Content by:** Tatum Rubald

**Goals:**

Model a wheel off of an actual disc golf CAD file.

**Content:**

See attached file. Same dimensions as Friss wheel.

**Conclusions/action items:**

Send into protolabs and have then evaluate its injection moldability.

---

TATUM RUBALD - Mar 08, 2023, 3:27 PM CST



[Download](#)

DiscGolf\_1\_.SLDPRT (346 kB)



## 3/3: Test Method

TATUM RUBALD - Mar 07, 2023, 8:23 AM CST

**Title:** Test Method for Wheel Loading

**Date:** 3/3

**Content by:** Tatum Rubald

**Goals:**

We want to make a test method that is fully repeatable and easy to understand.

**Content:**

*Loading*

### A.1.1 Loading

Prepare test subjects by giving them an unwound GW and the wheel and instruct them that they will wind the GW and place it into the wheel. Then test subject starts trial:

*Test Subject Trial Instructions:*

(Timer is started by test admin)

1. Wind guidewire by hand into a loop
2. Pick up wheel from table
3. Use one hand to hold wheel, one to hold wire-loop
4. Slide wire-loop into wheel
5. When guidewire is fully secured within the wheel, place wheel in one hand

(Timer is stopped by test admin)

\*If the guidewire is not able to load properly, record load time as MT (mistrial)

### A.1.2 Test Admin: Grade the Load Trial (0-3)

1. The test admin watches the test subject load GW into the wheel.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to load GW
1	The GW was placed in the wheel, but there were significant issues (i.e. had to manually maneuver the GW to fit into the wheel), The wheel may be unable to dispense GW after load.
2	GW slid into the wheel with ease, but there were minor issues (i.e. the tip of the GW hung out too far, took longer to load the wheel than usual, etc.), and the wheel was ready to be dispensed.
3	GW slid into wheel without complications

**A.1.3 By User: Comfortability (1-3)**

1. The user loads the GW from the wheel
2. Based on the table below, the user grades the load trial.

Comfort	Definition
1	Uncomfortable and awkward to load the GW into the wheel
2	GW is loaded with some minor issues/awkwardness and required assistance (ie: Held the wheel device wrong, could not load guidewire, did not know what to do with wheel and guidewire)
3	GW is loaded without complications and no awkwardness, high comfortability and loading with ease (ie: the wheel device was intuitive, did not need any additional assistance)

**A.1.4 Data Table**

Trial                      Guidewire Specs    Load Time                      Test Admin Grade    User Comfortability

**Conclusions/action items:**

This will be used as we test with residents.





## 3/8: Urethane Casting for Mold Prototype

---

TATUM RUBALD - Mar 08, 2023, 3:39 PM CST

**Title: Urethane Casting for Mold Prototype**

**Date:** 3/8

**Content by:** Tatum Rubald

**Goals:**

One of our goals for the end of the semester was to have the mold finalized. However, the professional mold for injection molding is over \$1000, so I want to research alternatives that we can do cheaper and that mimic injection molding processes/requirements.

**Content:**

<https://www.outdesign.co/single-post/2017/11/16/low-volume-cost-effective-alternatives-to-->

- Urethane Casting is an alternative to injection molding, but without the high upfront costs or long lead times.
- A master pattern of the product is created using CNC machining or high resolution 3D printing with the required surface finish
- This pattern is then used to create a Urethane or silicone mold into which a suitable resin can be poured in order to create multiple copies of the product.
- The mold typically lasts for around 20 runs
- This method provides a wide range of resins that can mimic 'production grade' materials ranging from soft elastomers like silicone rubber to hard plastics like ABS

**Conclusions/action items:**

I will reach out to the makerspace to see if they do Urethane casting.



# 3/20: Casting Quote

TATUM RUBALD - Mar 21, 2023, 10:08 AM CDT

**Title:** Casting Quote from Fathom

**Date:** 3/20

**Content by:** Tatum Rubald

**Goals:**

Evaluate quote for Urethane Casting

**Content:**

Fathom came back with the attached quote for a Urethane casting. It includes: CNC machined master pattern, the Urethane casting mold in Silicone, and a PP-Urethane molded product.

It is \$528 for all parts.

**Conclusions/action items:**

This isn't a cheap option, but it is cheaper than making the injection molding-mold. Is there a way to make a silicone mold at home????

TATUM RUBALD - Mar 21, 2023, 10:07 AM CDT

**FATHOM**  
DIGITAL MANUFACTURING REIMAGINED

Fathom Mfg. Co. Inc.  
8277-FATHOM-8  
816 per ft @ Fathom Mfg. Co. Inc.

Quote	42492	Contact
QUOTE DATE: 3/17/2023	QUOTE MANAGER: Jody Kucak	COMPANY: Fathom
QUOTE REF: 42492-01	CONTACT: jody.kucak@fathommfg.com	ADDRESS: 2500 W. 100th St.
QUOTE REF: 42492-01	PHONE: 781.263.8122	PHONE: 781.263.8122

Part #	Rev	MANUFACTURER'S PRICE	QUANTITY	UNIT PRICE	TOTAL	ESTIMATED LEAD TIME
Standard 0.25MPPT Part # 424	Rev 01	Urethane Casting	1	\$410.00	\$410.00	10 business days
		NOTES				
		Color: Milk White				
		NOTES				
		Water and Milk Proof				
		NOTES				
		CNC Machined				

MATERIALS	QUANTITY	UNIT PRICE	TOTAL	ESTIMATED LEAD TIME
ABS	1	\$10.00	\$10.00	10 business days
PP	1	\$10.00	\$10.00	10 business days
Urethane	1	\$10.00	\$10.00	10 business days
Other	1	\$10.00	\$10.00	10 business days

[Download](#)

Fathom-Quote42492.pdf (127 kB)



## 3/20: Simulated Injection Molding

TATUM RUBALD - Apr 04, 2023, 11:34 AM CDT

### Title: Simulated Injection Molding

Date: 3/20

Content by: Tatum Rubald

### Goals:

To find a way to simulate injection molding by a method other than Urethane casting. Find a way to make a mold on CAD and print it.

### Content:

<https://formlabs.com/blog/diy-injection-molding/>

Design Mold:

1. Download the blank mold insert design files—you'll use them to create your injection mold design.
2. Import both mold halves of the mold core and the 3D design you'd like to produce into your CAD tool.
3. Ensure that the object fully intersects with the inlet for the molten plastic during the injection molding process.

3D Print Mold:

1. essential to pick a material that can withstand the temperature and pressure on the mold during the injection molding process
2. Choose resin based on table:

CRITERIA	HIGH TEMP RESIN	GREY PRO RESIN	RIGID 10K RESIN
High molding temperature	★★★★	★	★★
Shorter cooling time	★★★★	★	★★
High pressure	★	★★	★★★★
Increase cycle number for complex geometries	★	★★	★★★★

Injection Mold Plastic Parts

1. Use bench top injection mold machine such as such as the Galomb Model-B100 or Holipress

### Conclusions/action items:

Summary: Use blender to create a mold. Software allows for download of master pattern, and mold is created by that. You can then 3D print the mold (in two halves), and then use a bench top injection molding machine to make product.

This seems do-able, but does the Makerspace have benchtop injection molding machines? Is there a way to manually melt and pour a plastic in to check the molds viability?





## 3/3: DiscGolf v2

---

TATUM RUBALD - Apr 04, 2023, 11:31 AM CDT

**Title:** DiscGolf v2

**Date:** 3/3

**Content by:** Tatum Rubald

**Goals:**

Redesign DiscGolf with chimney and greater height.

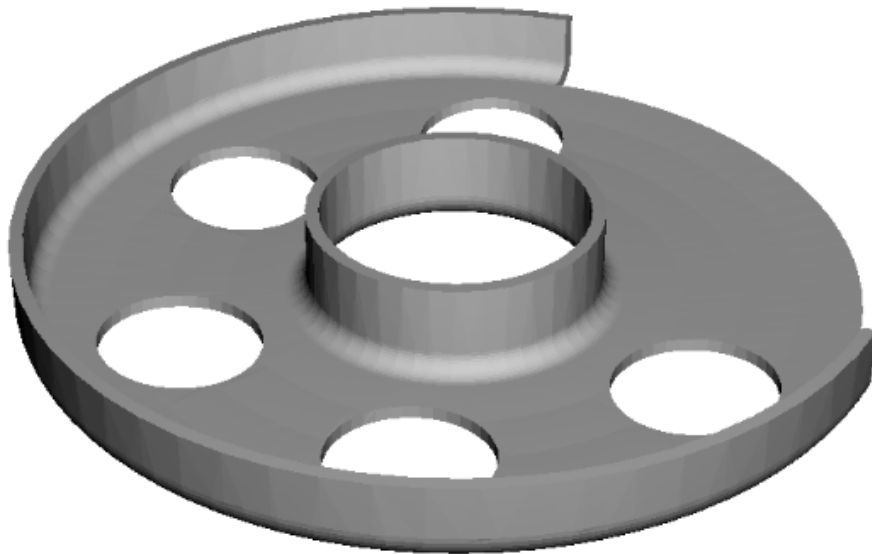
**Content:**

OD: 156 mm

Chimney ID: 27.5mm

Thickness: 4.5mm

Height: 17mm



**Conclusions/action items:**

See attached files.

TATUM RUBALD - Apr 04, 2023, 11:31 AM CDT



[Download](#)

**Disgolfv3.SLDPRT (241 kB)**

TATUM RUBALD - Apr 04, 2023, 11:31 AM CDT



[Download](#)

**Disgolfv3.STL (368 kB)**



## 4/01/2023 Tong Lecture

---

TATUM RUBALD - May 01, 2023, 12:38 PM CDT

**Title:** Tong Lecture

**Date:** April 1

**Content by:** Tatum Rubald

**Goals:** Summarize the main points from this years Tong Lecture. I was unable to attend in-person, so I watched a recording.

**Content:**

- Dr. Rasmussen, Badger Alumnus
- Entrepreneurship is characterized by a need for achievement or an achievement orientation which is a drive to excel, advance and grow
- Time and health are precious assets that we don't recognize until they present themselves
- There is no passion to be found playing small- in settling for a life that is less than the one you are capable of living
- Passion, purpose, persistence , curiosity , commitment, confidence, resilience, resourcefulness, reliability
  - remain curious
- Entrepreneurs do things in a new and better way and make decisions under certainty
- The most successful I people in life are the ones who ask questions. They're always learning. They're always growing.

**Conclusions/action items:**

It was cool to her about Dr. Rasmussen's experience of being an entrepreneur. I love hearing from women in the field, and it was very inspiring.



## 16FEB2023: Goals for Team

---

TATUM RUBALD - Feb 21, 2023, 9:49 AM CST

**Title:** Goals for Team

**Date:** Feb 16

**Content by:** Tatum Rubald

**Goals:**

Send message to team about upcoming goals.

**Content:**

- Should probs decide on the journal we are going to use soon.
- Victoria and Lily, do you have one u feel strongly abt?
- Ben, could u reach out to protolabs and ask what material would make the current overhang possible? And in general, how much overhang can be present?
- Addie, can you coordinate a time with Dr. y for testing with residents?
- Me- I am going to find a frisbee cad file and play around with it, seeing how much overhang is on there

**Conclusions/action items:**

Dr. Y is out of town until 2/25.





## 4/24 Collapsible Molding

---

RACHEL KRUEGER - May 01, 2023, 12:08 PM CDT

**Title:** Collapsible Molding

**Date:** 4/24/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Present articles that show the ability to use collapsible molding.

**Content:**

These two articles describe the process of a collapsible mold and confirm ability for use with undercuts. These outline the general information.

[Collapsible core injection molding | plasticmold.net](#)

[How to Advance Molding Undercuts with Collapsible Core Design | MoldMaking Technology](#)

here is an article to use that shows that even more complex designs can use this type of molding and that it works for undercuts.

[A two-stage collapsible core for injection moulded plastic parts with internal undercuts - ScienceDirect \(wisc.edu\)](#)

**Conclusions/action items:**

Conclude that collapsible molding is a feasible option for our design.



## 2/13/2023 Labeling

RACHEL KRUEGER - Feb 13, 2023, 12:58 PM CST

**Title:** Labeling for Finished Device

**Date:** 2/13/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Outline specifications for FDA approved labeling of devices.

**Content:**

1. FDA requirements for labeling of medical devices

1. Name and location of manufacturer, packer, or distributor
2. Definitions and intended use

1. Examples of definitions we would need to include: *Device package* means a package that contains a fixed quantity of a particular version or model of a device. *Expiration date* means the date by which the label of a device states the device must or should be used. *FDA, we, or us* means the Food and Drug Administration. *Finished device* means any device or accessory to any device that is suitable for use or capable of functioning.

3. Directions for use (in this case would be how to load and unload wires)

1. Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

4. [CFR - Code of Federal Regulations Title 21 \(fda.gov\)](https://www.fda.gov).

2. Sterile devices:

- o warning shall be included in case only a part of the device is sterile
- o attention shall be given when re-sterilization is not recommended
- o adequate information shall be given for devices which are intended to be sterilised before use by the user.

3. UDI requirements: FDA-related UDI requirements are quite complex and will be explained in details in a different post coming soon. Currently, all the devices sold in United States must bring a UDI in the device label and on the package. Furthermore, all the devices subject of UDI requirements need to be registered in a specific public database called [GUDID](https://www.fda.gov/gudid).

4. ISO 20417 checklist for compliance

5. medical devices: ISO 15223-1 and ISO 20417

6. [FDA Labelling Requirements for Medical Devices: An Overview \(qualitymeddev.com\)](https://www.qualitymeddev.com)

**Conclusions/action items:**

Ensure final packaging follows FDA and ISO standards.



## 2/13/2023 Clean Room Requirements

---

RACHEL KRUEGER - Feb 13, 2023, 1:06 PM CST

**Title:** Clean Room Packaging/Assembly

**Date:** 2/13/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Outline requirements for clean room verification, assembly, and packaging.

**Content:**

General cleanroom requirements:

1. **Internal surfaces:** Every surface in the cleanroom should be smooth and impenetrable by microorganisms. They should also be strong enough not to crack or shatter besides being easy to clean. The materials for the surfaces shouldn't create flakes or dust.
2. **Airflow:** A cleanroom's airflow system should be effective at circulating particles out of the room. Facilities usually use air filters to clean out contaminants such as vapor, moisture, or particulates. Air can be recirculated after cleaning or fresh air pumped into the cleanroom as a replacement.
3. **Employee access:** The number of people allowed into a cleanroom should be strictly controlled and only specially-trained personnel given access. Managing people who go in and out of a cleanroom is given the highest priority as human beings are the largest source of contaminants.
4. The level of cleanliness in cleanrooms is quantified by the number of particles in every cubic meter at a predetermined molecule measure. Class 1 facilities have the lowest level of contaminants while Class 9 facilities have the highest. The typical urban outdoor air has 35,000,000 particles per cubic meter at a 0.5-micrometer size range. This is the same as an ISO 9 cleanroom. An ISO 1 cleanroom contains 12 particles per cubic meter at a size range of 0.3 micrometers. At 0.5 micrometers, an ISO 1 cleanroom doesn't have any particles.
5. The minimum standards for ISO 7 cleanrooms include:
  1. An air change rate of 60 to 90 per hour
  2. Mandatory testing every six months according to ISO 14644-2 guidelines
  3. A separate gowning room
  4. 352,000 particles per cubic meter at 0.5µm
  5. HEPA filters
6. [Everything You Need To Know: Cleanroom Classifications, Requirements, Standards and ISO Class - Neslo Manufacturing](#)

**Conclusions/action items:**

Ensure the cleanroom we designate is ISO class 7 or greater.



## 2/13/2023 Materials

RACHEL KRUEGER - Feb 13, 2023, 1:24 PM CST

**Title:** Injection moldable materials that can be used in the OR

**Date:** 2/13/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Find possible materials to use for final market device.

**Content:**

1. First will outline the best injection molding materials then compare to see which qualify for operating room use.
2. Best injection molding materials:
  - Polypropylene (PP): High chemical and moisture resistance, flexibility, toughness, and excellent electrical insulation make polypropylene highly suitable for injection molding. The common applications can be found in the food packaging industry. Washing and cleaning are also easy without degradation and damage chemicals. Mixing with foods is not a scenario with packaging made of PP. That's why it is safe for human contact, and moisture resistance keeps the inside warm and fresh for a prolonged period of time.
  - Nylon: Good chemical and thermal resistance, high melting temperature, high toughness, and brittleness make it one of the injection molding materials suitable for applications like mechanical parts, gears, bushing, bearings utilized mostly in automobile and electrical industries.
  - Acrylic: It is often utilized as a suitable alternative for glass and even its alternative Polycarbonate for manufacturing windows, doors, transparent walls, display products lenses, fashion accessories, and even lighting equipment for the construction industry.
  - Acrylonitrile Butadiene Styrene (ABS): Key properties include toughness, scratch resistance, impact resistance, and good dimensional stability. ABS is widely used in the electronics industry for manufacturing computer keyboards, power tool housings, phone adapters, wall socket plastic guards, and even lego toys. It is one of the few injection molding materials with the strength and agility required to be utilized in electronics.
  - High-Density Polyethylene (HDPE): HDPE has low-temperature resistance, high tensile strength, good chemical resistance, and excellent electrical insulating properties. It is mostly used for food packaging applications like bottles of milk and juices, crates, trays, etc., and textile applications like ropes, decorative fabrics, fishing nets, etc.
  - Polyoxymethylene (POM): With excellent wear resistance, high crystallinity, and fantastic dimensional stability, good resistance to organic solvents makes POM one of the prime injection molding materials. POM's high-end properties make it suitable for applications in industries like automobiles, healthcare, and consumer goods. Main products made from POM include ball bearings, knives, fasteners, pipe couplings, showerheads, automobile cushioning interior, etc.
  - Polycarbonate (PC): Major properties include high impact strength, good abrasion resistance, excellent chemical resistance, great steam resistance (not affected by water or temperature), withstanding prolonged steam sterilization, etc. Major products producing PC are coffee machines, food mixers, light housings, headlamp bezels, security windows, shelters, safety goggles, lenses, food storage containers, food processors, etc.

- Polyethylene (PE): Some of the major properties are phenomenal resistance to most solvents (except hydrocarbons), great electrical insulating properties, inexpensiveness, and decent water resistance. Products made from PE include oil and liquid food containers, housewares, ice-boxes, toys, jerry cans, drums, pharmaceutical packaging, squeeze bottles, caps, pipes, garbage containers, etc.
- Thermoplastic Rubber (TPR): Like many other injection molding materials on the list, TPR is recyclable, which increases its applicability and helps manufacturers control their carbon footprint. Its boasts fantastic chemical and weather resistance coupled with high-impact strength. Major products made from thermoplastic rubber are cable jacketing, footwear, automobile components, toys, soft handles and grips, window and door weather stripping, coated fabrics, household appliances, etc.
- Polystyrene (PS): Major polystyrene properties are high chemical and heat resistance, high UV stability, and high dimensional stability. The most common applications are CD and DVD cases, food trays and containers, egg cartons, toys, automobile parts, gardening tools, equipment, etc.
- [Top 10 Injection Molding Materials \(And Why They are the Best\) - PlasticRanger](#)

3. Which of these are common to be used in the operating room:

1. Polypropylene, ex: irrigation bottles
2. Nylon, ex: sutures
3. HDPE, ex: sheets
4. Polyethylene, ex: sanitation and hygiene

**Conclusions/action items:**

Explore characteristics of the injection moldable materials along with compatibility in the OR.



## 3/5/2023 Warf Patent Review

---

RACHEL KRUEGER - Mar 05, 2023, 7:36 PM CST

**Title:** Warf Patent Review

**Date:** 3/5/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Outline what information we will need to disclose in order to submit a patent review to warf

**Content:**

1. Locate the innovation disclosure information page
2. IP manager at warf if applicable
3. Write down all the innovators along with UW department
4. Submit a title and description
5. Attach any applicable documents (journal, images, drawings, etc.)
6. Make a case for why this innovation is better or needed
7. Describe how we expect the innovation to be implemented
8. Link any non-confidential documents such as presentations
9. Submit and wait to be assigned a case manager
10. [Innovation Disclosure | Wisconsin Alumni Research Foundation \(warf.org\)](https://warf.org)
11. Dr. Y has been in communication with a company regarding a patent but haven't gotten very far

**Conclusions/action items:**

Fill out this form to get the ball rolling on a patent.



## 3/5/2023 Injection Molding - Overhang

---

RACHEL KRUEGER - Mar 05, 2023, 7:52 PM CST

**Title:** Injection Molding - Overhang

**Date:** 3/5/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Identify possible solutions to the overhang issue.

**Content:**

1. Use a lifter
  1. Angular component ejection mechanism
2. Use a softer material to allow it to be pushed out of the mold without breaking
3. Use parting lines
  1. We had discussed this in the past and we don't think this would be best given the cost and extra steps required to have a finished part
4. Side actions
  1. Similar to parting lines but splits the mold in two and rotates the piece so that the overhang is able to be ejected
  2. Best materials for this: rigid materials like nylon, polycarbonates, and acetyl
5. Bumpoffs
  1. Good for molding lens covers, container caps, and similar functions that require a snap in place
  2. An insert is machined so an undercut can be applied and is bolted into the mold where a pocket matches the insert dimensions
  3. Best materials: LDPE, thermoplastic elastomer, and thermoplastic polyurethane
6. Hand loaded inserts
  1. Not a good option for our application
7. Telescoping shutoffs
  1. Requires splitting the part in two pieces
8. [Design Tip: 6 ways to achieve undercut success in molded parts \(protolabs.com\)](https://www.protolabs.com/design-tip/6-ways-to-achieve-undercut-success-in-molded-parts/)

**Conclusions/action items:**

Side actions and bumpoffs are the best options for our application.



## 3/21/2023 Survey Questions For Testing

RACHEL KRUEGER - May 01, 2023, 9:50 PM CDT

**Title:** Survey Questions For Testing

**Date:** 3/21/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Create 5-8 questions for cath lab techs to answer after testing.

**Content:**

1. Using the current method of storing guidewires under a wet towel while in the operating room, how many issues does this cause in terms of contamination resulting in the need for a new wire? Please rank on a scale of 1-5:
  1. This method never causes contamination
  2. This method has caused contamination very few times in my experience
  3. This method causes contamination about half of the time
  4. This method causes contamination more often than not
  5. This method causes contamination every or nearly every time
  6. (N/A) I have never used this method
2. Using the current method of storing guidewires under a wet towel while in the operating room, how often does this cause the guidewire to kink, tangle, or become disorderly? Please rank on a scale of 1-5:
  1. This method never causes these issues
  2. This method very rarely causes these issues
  3. This method causes these issues about half of the time
  4. This method causes these issues more often than not
  5. This method causes these issues every or nearly every time
  6. (N/A) I have never used this method
3. Using the method of storing guidewires under a wet towel while in the operating room, do you feel this method is the most efficient and cost effective method?
  1. Yes, this method causes little disruption in the operating room and is inexpensive
  2. Maybe, this method is inexpensive but often results in complications in terms of contamination and function of the wire
  3. No, this method often results in complications in terms of contamination and function of the wire and does not outweigh the cost benefit
  4. (N/A) I have never used this method
4. Given your experience with guidewire use and storage, what do you rank your desire for a new storage method of guidewires on a scale of 1-5?
  1. I have no desire for a new storage method
  2. I have given very little thought for a new storage method but am not opposed
  3. I am indifferent to a new storage method
  4. I would prefer a new storage method if it is more efficient and less likely to have issues in the operating room than the current method
  5. I absolutely would prefer a new storage method
  6. (N/A) I have never used this method
5. Using the method of storing guidewires with a cath clip, how often does this result in contamination? Please rank on a scale of 1-5:
  1. This method never causes contamination
  2. This method very rarely causes contamination



3. This method causes contamination about half the time
  4. This method causes contamination more often than not
  5. This method causes contamination every or nearly every time
  6. (N/A) I have never used this method
6. Using the method of storing guidewires with a cath clip, how often does this method result in disorderly, kinked, or tangled wires? Please rank on a scale of 1-5:
1. This method never causes these issues
  2. This method rarely causes these issues
  3. This method causes these issues about half the time
  4. This method causes these issues more often than not
  5. This method causes these issues every or nearly every time
  6. (N/A) I have never used this method
7. Using the method of storing guidewires in the Medline bowl, how often does this result in contamination of the wire, which then requires a new wire? Please rank on a scale of 1-5:
1. This method never causes contamination
  2. This method very rarely causes contamination
  3. This method causes contamination about half the time
  4. This method causes contamination more often than not
  5. This method causes contamination every or nearly every time
  6. (N/A) I have never used this method
8. Of the three storage methods discussed, please rank your preference of each method from least prefer (1) to most prefer (3): wet towel, cath clip, medline bowl.
- 1.
  - 2.
  - 3.
  4. (N/A) I have never used this method

**Conclusions/action items: Send this survey to Dr. Y to send out to residents and cath lab techs.**



## 3/31/2023 Tong Lecture

---

RACHEL KRUEGER - Apr 01, 2023, 12:51 PM CDT

**Title:** Tong Lecture Reflection

**Date:** 3/31/2023

**Content by:** Rachel Krueger

**Present:** Rachel Krueger

**Goals:** Outline takeaways and main points of tong lecture

**Content:**

1. I was unable to attend the in-person lecture, so I watched a previous recording
2. Speaker: Doug Dietz
3. Experience: Innovation architect/GE Healthcare
4. Looking at the human side of healthcare and how to get to the reality of what really matters
5. Creating a "jungle adventure" to help children ease their worries about the scariness of healthcare equipment
6. Creating a "coral city adventure" to make the children feel they are in a yellow submarine, not in a hospital
7. They can add visuals to ease worries, scents to distract from the medical aspect, or calming music
8. Creating a "cable car adventure" so the kid gets picked up and 'driven' in, instead of feeling like they are just in a machine
9. "Remote Mammo" - met an isolated mother living in a remote village. They realized most women totally neglect their own healthcare and put their families needs first. If all women could receive both emotional and physical support for their healthcare needs without leaving their village, it would change the world.

**Conclusions/action items:**

Often, each individuals needs and fears are overlooked when designing medical technology. By designing the technology with their needs and fears in mind, people would be much more willing and able to seek treatment.



## Guidewire Procedure Complications - 2/23/23

VICTORIA HEILIGENTHAL - Feb 23, 2023, 9:09 AM CST

**Title:** Guidewire Procedure Complications

**Date:** 2/23/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To understand current statistics on complications in guidewire procedures

**Content:**

- Spinal procedures
  - Risk ranges from 0.4%-14.8%
  - Complications: guidewire breakage, cerebrospinal fluid leak, infection, ileus, hardware failure
  - Causes: breakage and migration of guidewire (metal failure), poor use of guidewire, lack of tactile or visual feedback
  - [The complications associated with guidewire use in spine surgeries involving pedicle screw placement: A comprehensive literature review | Pracyk | Case Studies in Surgery \(sciedupress.com\)](#)
- Central vein catheterization
  - 12% failure risk
  - Complications: bleeding, clot formation, infections, air embolism, perforation of veins, hematoma formation, kinking or loop of guidewire tip, breakage of guidewire
  - [Guidewire Mishap: An Avoidable Iatrogenic Complication - PMC \(nih.gov\)](#)
- Central venous line placement
  - 15% complication risk
  - Complications: arterial puncture, hematoma, arrhythmia, infection, clot formation, air or guidewire embolism, lost guidewires
  - [Loss of Guide Wire as an Important Complication of Central Venous Catheterization; a Case Report - PMC \(nih.gov\)](#)

**Conclusions/action items:** This information can be used to understand why the use of guidewires is important during surgery



## Failure of Complications in Medline Bowl - 2/20/23

VICTORIA HEILIGENTHAL - Feb 23, 2023, 8:58 AM CST

**Title:** Failure of Complications in Medline Bowl

**Date:** 2/23/23

**Content by:** Victoria

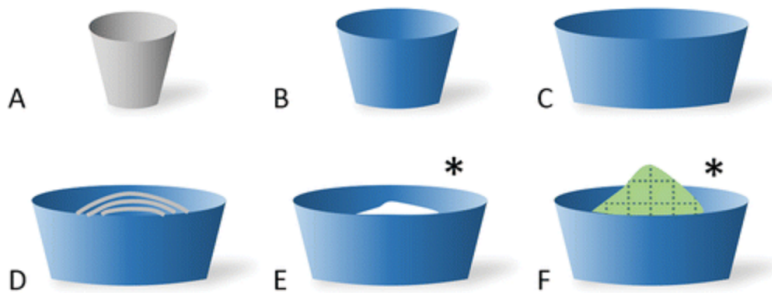
**Present:** N/A

**Goals:** To document problems with competing designs currently on the market and to address how our design addresses those problems

**Content:**

[Preventing Inadvertent Foreign Body Injection in Angiography | Radiology \(rsna.org\)](https://www.rsna.org)

This study aim was to find the source of contamination particles that could lead to infections. These particles are typically found on the angiography table in the OR. Gauze and cotton fabrics have already been established as foreign particles in the OR. One of the conditions tested was a large plastic bowl and a guidewire with its sheath. Although not specifically stated that this bowl was the Medline Guidewire bowl, it can be assumed that this device is very similar to the Medline Guidewire bowl. The container was filled with saline and the particle count was tested every 0, 30, 60 minutes. Image D below is the device testing most similar to the Medline Guidewire bowl.



**Figure 2:** Schematic illustration of our experimental setups. *A*, Small metal cup; *B*, small plastic cup; *C*, large plastic bowl; *D*, large plastic bowl with guidewire and its sheath; *E*, large plastic bowl with stack of woven gauze; *F*, large plastic bowl with large cotton towel. All containers were filled with saline, which was then analyzed for particles. The control experiment with saline directly drawn from its bag is not shown, but its principle can be found in [Figure 3](#). \* Placing a stack of woven gauze and a cotton towel in the bowl resulted in a significant increase in the number of particles ( $P < .001$ ).

The bowl with the guidewire and its sheath had more particles than the large plastic bowl (mean, 5.0 particles per milliliter  $\pm$  1.2;  $P = .01$ ). After 30 minutes, the number of particles were significantly higher compared to when the guidewire was placed in the bowl (mean, 7.8 particles per milliliter  $\pm$  0.6;  $P = .02$ ).

These results show that particle contamination is a systemic issue, and not a single case. This study also shows that a large cotton towel in a bowl was a major source of contamination. This is a large reason as to why the current method of using a towel with the guidewire on the table is bad and needs a new solution.

**Conclusions/action items:** This information can be used by the team in the journal to prove why our device is needed on the market.



## Cath Clip Information-3/20/23

---

VICTORIA HEILIGENTHAL - Mar 20, 2023, 6:42 PM CDT

**Title:** Cath Clip Information

**Date:** 3/20/23

**Content by:** Victoria

**Present:** N/A

**Goals:** Figure out lead time and price on Cath Clip

**Content:**

[Order CathClip - CathClip - Device Management Tool to Improve Profitability and Safety/Outcomes](#)

I sent an email to the information/delivery email on the CathClip website. They got back to me and told me a single, non-sterile CathClip can be purchased for \$5 and they ship it out the same day you buy it.

**Conclusions/action items:** The team can use this information to decide when to order a CathClip for testing.



## Potential Journal Options - 2/2/23

VICTORIA HEILIGENTHAL - Feb 02, 2023, 12:15 PM CST

**Title:** Potential Journal Options

**Date:** 2/2/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To document journals the team could create the semester manuscript for submission

**Content:**

- CVIR
  - Aims and Scope
    - Publishes minimally invasive vascular surgical procedures
    - Manuscripts are related to venous and arterial procedures
    - Publishes new technologies
  - Standards/Submission Instructions
    - Provides guidelines for reporting
    - Instructions
      - [Endovascular journal - Submit - CVIR Endovascular - CIRSE's open access journal](#)

[CIRSE's open access journal - CVIR Endovascular - CIRSE's open access journal](#)

- Vascular and Endovascular Surgery (VES)
  - Aims and Scope
    - Reports newest surgical techniques
    - Publishes endovascular
  - Standards/Submission Instructions
    - [Manuscript Submission Guidelines: Vascular and Endovascular Surgery: SAGE Journals \(sagepub.com\)](#)
    - Seems to have more requirements for submission

[Vascular and Endovascular Surgery: SAGE Journals \(sagepub.com\)](#)

- Journal of Vascular Surgery
  - Aims and Scope
    - Endovascular and surgical care of vascular diseases
    - Publishes medical advances
  - Standards/Submission Instructions
    - [JVS\\_Instructions\\_for\\_Authors-1673285780243.pdf \(jvascsurg.org\)](#)
    - Very clear and organized on what is expected for the journal submission

[Home Page: Journal of Vascular Surgery \(jvascsurg.org\)](#)

**Conclusions/action items:** Using this information, the team can decide which journal to follow for the manuscript draft. From initial research, I think the Journal of Vascular Surgery or CVIR would be best since their submission standards are easily laid out and are not as complex and in-depth as the VES.



**Title:** Journal of Medical Devices

**Date:** 2/21/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To understand the requirements from the Journal of Medical Devices for the potentially using as the team's manuscript

**Content:**

It is important to know the guidelines from the Journal of Medical Devices since it is a more general journal. The previous journals researched were more specific to endovascular areas. However, if the team is not planning on submitting the manuscript at the end of the semester, it might be better to choose a more generalized journal like the Journal of Medical Devices.

- Purpose/scope
  - Presents papers on new medical devices to improve treatments and provide new research
  - Novel techniques and devices are presented
  - Very generalized scope, spanning in multiple areas of the medical field
- Journal types provided
  - Research or design innovation paper most relate to this project
    - 7,000-12,000 word papers
- Similar guidelines/requirements/structure of report as other journals already researched
  - Provides template on website

[asme\\_guide\\_for\\_journal\\_authors\\_final.pdf](#)

[Information for Authors - ASME](#)

[About | J. Med. Devices | ASME Digital Collection](#)

**Conclusions/action items:** The team can use this information to further decide which journal to use for the manuscript



VICTORIA HEILIGENTHAL - May 01, 2023, 12:20 PM CDT

**Title:** MATLAB Code**Date:** 5/1/23**Content by:** Victoria**Present:** N/A**Goals:** To document the code used for data analysis**Content:****Conclusions/action items:**

VICTORIA HEILIGENTHAL - May 01, 2023, 12:21 PM CDT

```

% Spring 2022
clear
clc
close all

% Load data
[dataFile, dataDir] = uigetfile('*.xlsx', 'Select excel file containing your study data');
load_noStead = 1;
load_competing = 2;
% load_noStead = 3;
% load = 4;
load_data = xlsread('402 Testing.xlsx', load_noStead);
% load_data = xlsread('402 Testing.xlsx', load_noStead);
competing_data = xlsread('402 Testing.xlsx', load_competing); % Change based on which sheet from excel

designWinCompete = competing_data(:, 2);
designWinLoad = load_data(:, 2);
designWinTime = load_data(:, 2);

loadTimeCompete = competing_data(:, 3);
loadGradeCompete = competing_data(:, 4);
loadComfortCompete = competing_data(:, 5);

% Average loading times for Friss
Friss = find([designWinLoad == 1];
Friss = load_data(Friss, :);

Friss_loadAvg = mean(Friss(:, 3), 'omitnan')
Friss_loadStd = std(Friss(:, 3), 'omitnan')

% Average unloading times for Friss
FrissUn = find([designWinLoad == 1];
FrissUn = load_data(FrissUn, :);
FrissUn([isnan(FrissUn(:, 3))]) = 0;

FrissUn_loadAvg = mean(FrissUn(:, 3), 'omitnan')
FrissUn_loadStd = std(FrissUn(:, 3), 'omitnan')

% Ratings for Friss
[rows, cols] = size(load_data);
FrissUnGrades = cell(rows, 5);

for x = 1
    designWin = find(designWinLoad == 1);
    designWin = load_data(designWin, :);
    xGradesFriss = xlsread(designWin(:, 3));
    xGradesFriss = sum([xGradesFriss]);
    occurGradesFriss = zeros(numel(xGradesFriss), 1);
    for k = 1:numel(xGradesFriss)
        occurGradesFriss(k) = sum(designWin(:, 4) == xGradesFriss(k));
    end
    emptyData = cellfun(@isempty, gradeTableFriss);
    emptyRows = find(emptyData(:, 1) == 2);
    nextRow = emptyRows(1);
    occurGradesFriss = [xGradesFriss; occurGradesFriss];
    numRow = numel(occurGradesFriss);
    % Design is 1st column (only Friss), rate is 2nd column, occurrences is 3rd
    column = gradeTableFriss(nextRow:nextRow+height(numRow)-1, :) = numRow;

```

[Download](#)**Endo\_guideS23.m (8.07 kB)**





## Running Statistics with Data-4/5/23

---

VICTORIA HEILIGENTHAL - May 01, 2023, 12:23 PM CDT

**Title:** Running Statistics with Data

**Date:** 4/5/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To understand which statistics test will be best to run on all of our data that we collect

**Content:**

[Analysis of variance \(ANOVA\) comparing means of more than two groups - PMC \(nih.gov\)](#)

[Statistical notes for clinical researchers: Chi-squared test and Fisher's exact test - PMC \(nih.gov\)](#)

Last semester, the team completed a one-way ANOVA test to compare the loading times across all the designs to determine if the differences were statistically significant. Since the team will be testing the current design against competitor designs, it will be important to use the one-way ANOVA test again. The ANOVA test will compare the means across all groups. In the past, the team has focused a lot of the loading and unloading times of the guidewire into the wheel. But since we are comparing the times to competing designs with very different operation methods, the data will most likely be statistical insignificant since the times will most likely be far off of each other. Due to this, it will be very important that the team analyzes the qualitative data that is collected through the surveys and the grading/rating of the loading and unloading to determine which device is the most efficient in keeping the guidewires organized and which device is easiest to use. To compare this qualitative data, the Fisher's exact test will be best since we are testing a small sample size. This test will help the team determine if the qualitative data collected across all devices tested are independent of each other, or if they all produce similar results.

**Conclusions/action items:** The team can use this information during data analysis



## Labeling on Packages - 2/21/23

---

VICTORIA HEILIGENTHAL - Feb 21, 2023, 9:29 AM CST

**Title:** Labeling on Packages

**Date:** 2/21/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To understand what packaging requirements are needed from the FDA

**Content:**

- General device labeling requirements
  - Name and place of business (including address)
  - Intended use and purpose of device
  - Specific directions on how to use
    - Include times, frequency, methods, preparation

[General Device Labeling Requirements | FDA](#)

**Conclusions/action items:** The team can provide this information to the client when handing off the project at the end of the semester



# Medical Grade Materials for Injection Molding-3/6/23

VICTORIA HEILIGENTHAL - Mar 07, 2023, 8:48 AM CST

**Title:** Medical Grade Materials for Injection Molding

**Date:** 3/6/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To document the medical grade materials that Protolabs offers

**Content:**

[PEEK, PEI, LSR and Other Material Options for Medical Prototyping \(protolabs.com\)](https://www.protolabs.com/peek-pe-ppsu-material-options)

MATERIAL	INJECTION MOLDING	CNC MACHINING	3D PRINTING
PEEK, PEI, PPSU	X	X	
POLYCARBONATE	X	X	
LIQUID SILICONE RUBBER	X		
TITANIUM		X	X
ABS-LIKE WATERSHED			X

MATERIAL	PLASTIC	METAL
PEEK, PEI, PPSU	X	
POLYCARBONATE	X	
LIQUID SILICONE RUBBER	X	
TITANIUM		X
ABS-LIKE WATERSHED	X	

MATERIAL	TEMP RESISTANCE	GOOD CLARITY	LIGHTWEIGHT	SUITABLE FOR SKIN CONTACT
PEEK, PEI, PPSU	X			
POLYCARBONATE		X		
LIQUID SILICONE RUBBER	X			X
TITANIUM	X		X	
ABS-LIKE WATERSHED		X		

Based on these figures, PEEK/PEI/PPSU, Polycarbonate, or liquid silicone rubber would best match most of the team's material requirements. PEEK and PEI have long-term biocompatibility and sterilization.

**Conclusions/action items:** These material characteristics can be used to help determine what type of material the team should recommend for manufacturing.



## BPAG Meeting-2/17/23

---

VICTORIA HEILIGENTHAL - Feb 21, 2023, 11:38 AM CST

**Title:** BPAG Meeting

**Date:** 2/17/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To document what occurred at the BPAG meeting

**Content:**

This BPAG meeting was similar to previous BPAG meetings in the past. Documenting purchases, understanding the budget, and keeping orders on track was the main focus. An added piece to this semester was in regard to reimbursements from the university. The university will not be providing reimbursements this semester. If any UW funds are used, the client must make the purchases directly.

**Conclusions/action items:** Knowing the change with reimbursements from the university is important for the team to think about moving forward this semester



## Make-up Tong Lecture-4/11

---

VICTORIA HEILIGENTHAL - Apr 11, 2023, 6:36 PM CDT

**Title:** Make-Up Tong Lecture

**Date:** 4/11

**Content by:** Victoria

**Present:** N/A

**Goals:** To document notes from a previous Tong Lecture since I was unable to attend the lecture this year

**Content:**

Presented by Cathy Rasumussen

- Entrepreneur
  - An innovator or developer who recognizes and seizes opportunities
  - Turn opportunities into marketable ideas
  - Assumes risk of competitive marketplace to implement ideas
- Make an idea into something marketable to make a difference
- Intent: treating complex skin defects
  - Standard treatment for severe burns requires harvest of uninjured skin creating painful donor sites
  - Scar occurs at site of harvested donor skin
  - Goal: reduce/eliminate need for donor site skin harvest
- Impact: StrataGraft skin substitute
  - 2 decades of work for skin cell therapy
- Put yourself out there as an entrepreneur who wants to make a change
  - Have a distinct purpose
  - Have resilience and resourceful (know what is available)
- Key things for entrepreneur
  - Innovation
  - Management
  - Risk-tolerance (need to be comfortable with risk you take)
  - Opportunity (see where can help within the group)
- Formal education, self-education, foster creativity, seek new connections and experiences (listening and work on)
  - Have a great network from multiple people around you
- Its okay to make mistakes and have failures
  - Mistakes take you to where you need to be
  - Helps you grow and learn new important things
  - Don't be scared
- Leadership
  - Own your successes, but acknowledge you have an advantage
  - Show respect and build trust
  - Never ask your team when you wouldn't do it
- Team
  - Build the best team
  - What are they bringing to the table? What is their work ethic?
- Find a mentor
  - Be a mentor

- Pay it forward to the next generation
- Always learning something new
- Limits
  - Know your own limits
  - Do not spread yourself too thin
  - Don't give up
  - Need a good support group
- Be genuine, be yourself, be kind to yourself and do not devalue your own worth
- Be a light in the world

**Conclusions/action items:**



## Final Poster Presentation Recording - 5/1/23

---

VICTORIA HEILIGENTHAL - May 01, 2023, 12:21 PM CDT

**Title:** Final Poster Presentation Recording

**Date:** 5/1/23

**Content by:** Victoria

**Present:** N/A

**Goals:** To document my portion of the poster since I was unable to attend poster presentations

**Content:**

**Conclusions/action items:**

---

VICTORIA HEILIGENTHAL - May 01, 2023, 12:22 PM CDT



[Download](#)

402\_Presentation\_VH.mp4 (24.6 MB)



## 2/8/23 FRIS Wheel Quote

LILY GALLAGHER - May 02, 2023, 9:21 AM CDT

**Title:** FRIS Wheel Quote (Protolabs)

**Date:** 2/8/23

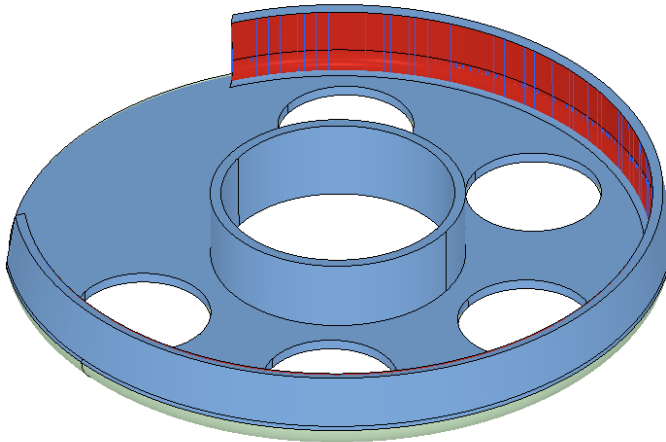
**Content by:** Ben Smith

**Goals:** Evaluate quote from Protolabs for injection molding the FRIS wheel design

**Content:**

Notes:

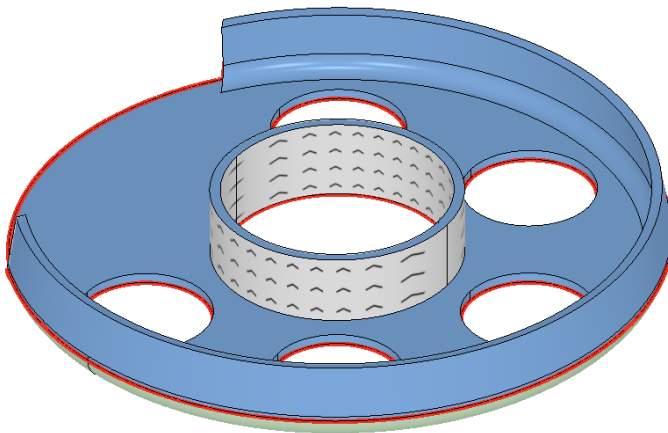
- Side wall on wheel features an overhang that undercuts part of the wheel. Because of this, the wheel cannot be injection molded as it would be impossible to pull it off of the mold.



○

○ **Figure 1: Wheel with highlighted areas where the wheel features an overhang.**

- Areas with arrows in image below need at least a 1.0 degree draft to avoid possible defects during milling and ejection

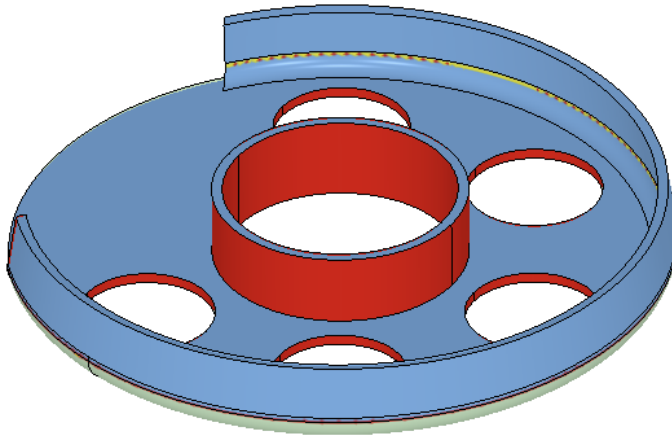


○

○ **Figure 2: Shows where a 1.0 degree draft is needed**

- Areas highlighted red in image below need a draft of at least 3.0 degrees if texture is wanted on the wheel

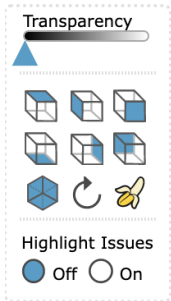




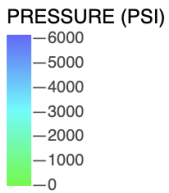
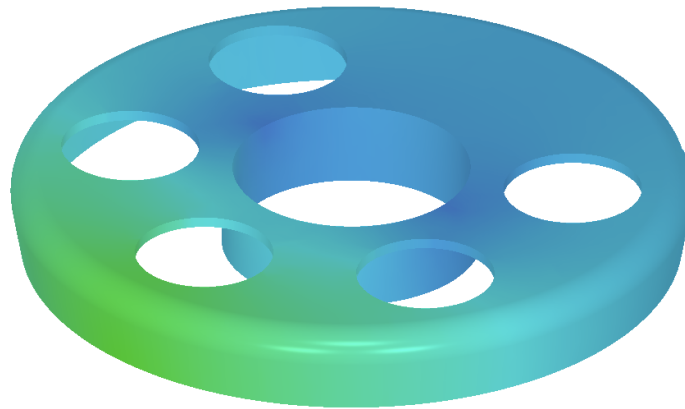
o

o **Figure 3: Shows where increased draft is needed for textures**

- Certain areas of the wheel will experience greater pressure during injection of plastic



1 in



o

o **Figure 4: Pressure gradient showing areas of high and low pressure during injection**

- Total Cost of Wheel Mold: \$5,595

**Conclusions/action items:**

As it is currently designed, the wheel is not injection moldable and needs some design revisions before we can proceed with injection molding.

**PROLABS**  
Manufacturing. Simplified.

Quote Date: February 8, 2023

Quote 0720-907 Prepared for UW Madison

Injection Molding (1/1)

Part: **FRIS Wheel**  
 Part Number: 0720-907  
 Current Revision: 1  
 Material: Nylon  
 Quantity: 1000  
 Dimensions: 1.500 x 1.500 x 0.500  
 Material: PA 12  
 Quantity: 1000  
 Dimensions: 1.500 x 1.500 x 0.500  
 Material: PA 12  
 Quantity: 1000  
 Dimensions: 1.500 x 1.500 x 0.500

Price Breakdown:

20 Parts @ \$34.54	\$690.80
Material	\$0.00
<b>Total</b>	<b>\$690.80</b>

Shipping To: 53703

Shipping Cost: No carrier rates are available.

Order Summary

Part: FRIS Wheel  
 Quantity: 1000  
 Price: \$0.00  
 Total: \$0.00

Thank you for the opportunity to quote your parts.

[Download](#)

Quote\_0720-907.pdf (264 kB)



## 2/8/23 Stand Quote

Ben Smith - Feb 08, 2023, 2:13 PM CST

**Title:** Stand Quote (Protolabs)

**Date:** 2/8/23

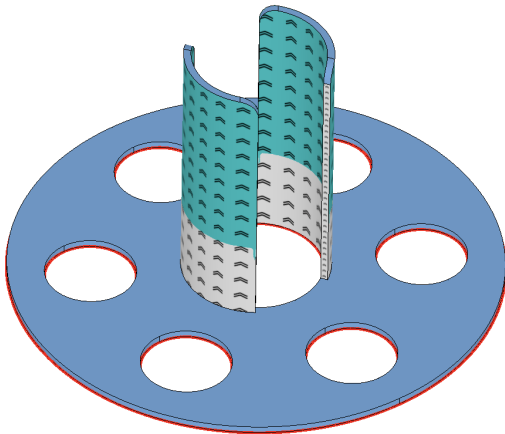
**Content by:** Ben Smith

**Goals:** Present the information given in the injection molding quote for the stand from Protolabs

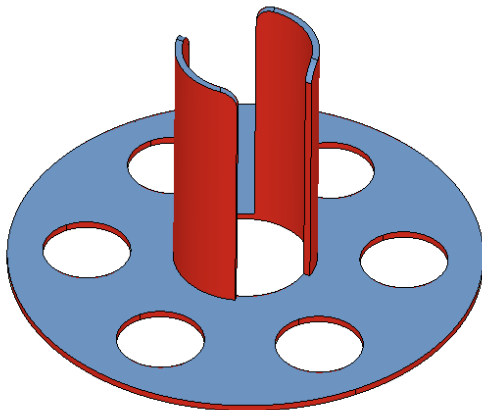
**Content:**

Notes:

- As the stand is currently designed, it is unable to be injection molded. However, not much redesign is required to make it injection moldable.
- A 2.0 degree draft is required for sides with arrows on them (shown below)



- 
- **Figure 1: Arrows on stand are areas needing a least a 2.0 degree draft**
- Faces shown in red below need a draft of at least 3 degrees



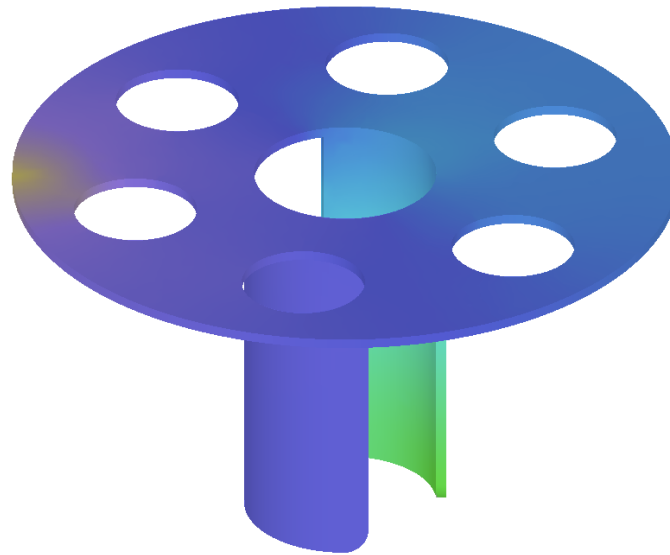
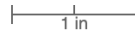
- 
- **Figure 2: Red areas show portion of stand needing at least 3.0 degree draft**
- Certain portions of the stand will be subjected to more pressure than others (shown below)

Transparency

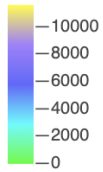


Highlight Issues

Off  On



PRESSURE (PSI)



o

o **Figure 3: Graphic showing pressure gradient experienced by stand while injection molding**

- Total Stand Mold Cost: \$5,820.00

### Conclusions/action items:

As it is currently designed, the stand is not injection moldable. Draft is necessary to be added to some faces before we can proceed with injection molding.





## 3/5/23 Disc Golf Design Quote

Ben Smith - Mar 07, 2023, 2:05 AM CST

**Title:** Disc Golf Design Quote

**Date:** 3/5/32

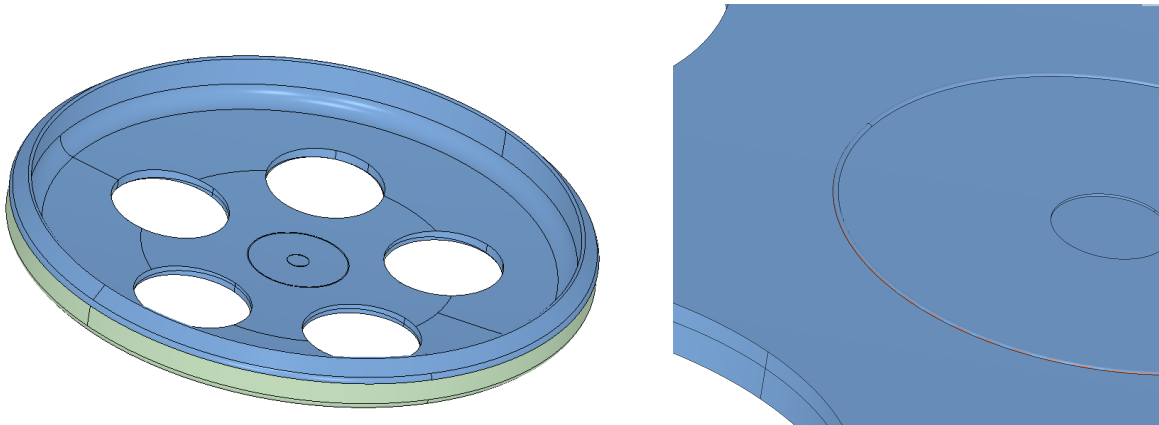
**Content by:** Ben

**Goals:** Evaluate the injection molding quote for the disc golf design and make plan for moving forward with the feedback

**Content:**

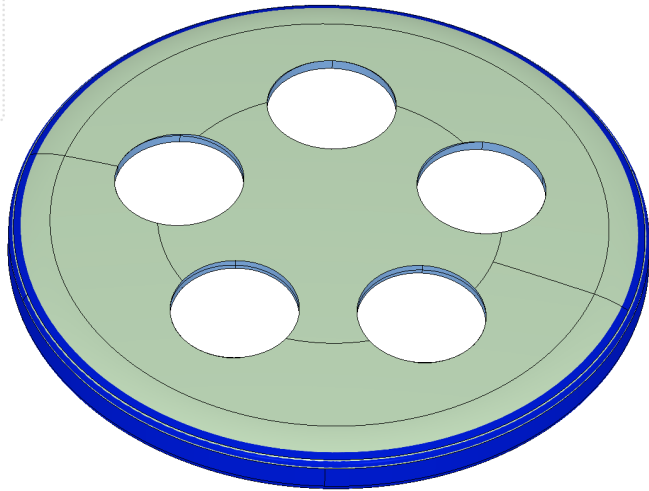
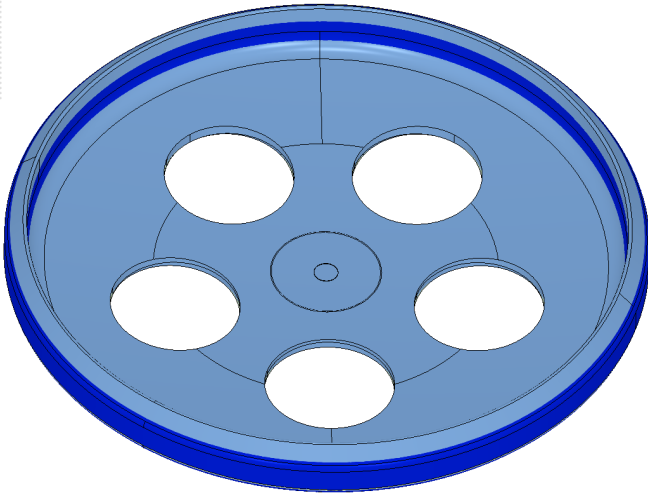
Notes:

- Areas highlighted orange below are too thin and need to be thickened to a minimum of 0.66mm



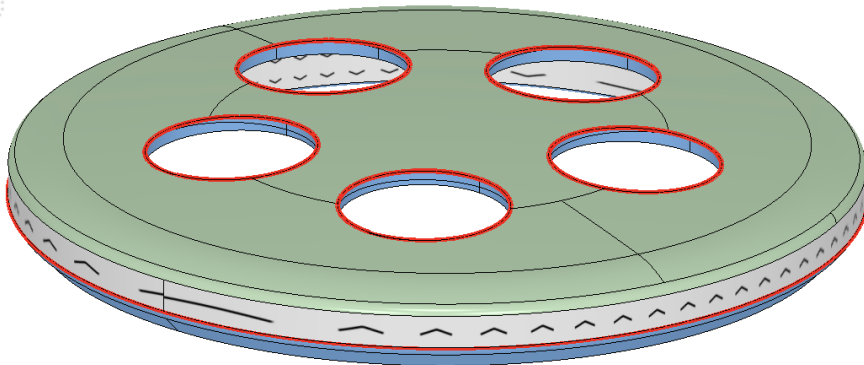
**Figure 1:** Area highlighted orange is too thin

- The features highlighted in RED below are too shallow to manufacture
- There needs to be a minimum depth of 0.13mm



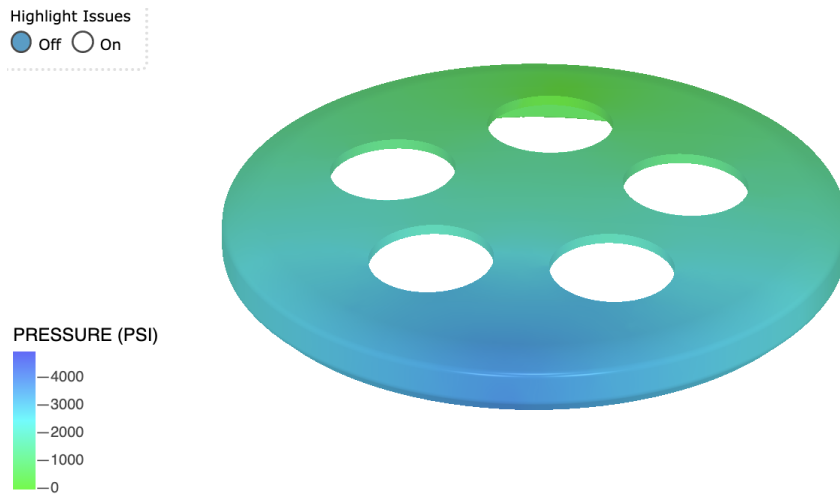
**Figure 3: Shows areas that are too thick and could lead to deformities**

- Draft aids in milling and ejection of this part.
- The areas indicated show faces with insufficient draft. A minimum of  $1^\circ$  draft is suggested in order to avoid possible cosmetic defects during milling and ejection.
- If we choose a textured finish on our part: PM-T1 requires at least  $3^\circ$  of draft, and PM-T2 requires at least  $5^\circ$  of draft.



**Figure 4: Areas showing where a draft is recommended**

- Certain portions of the stand will be subjected to more pressure than others (shown below)



**Figure 5: Shows what pressures the piece will be subjected to**

Total Cost of Mold: \$5,735.00

**Conclusions/action items:**

Overall, this design requires less changes to be injection moldable compared to the others we have quoted. After testing is completed and the results are analyzed, the team will need to consider which design is the best to move forward with.



**PROLABS**  
Manufacturing. Reimagined.

Quote Date: Mar 7, 2023

Quote #771-341 Prepared for UW Madison

Injection Molding (1/1)

**Disc Golf Discs**

Quantity: 20  
Part Name: Disc Golf Discs  
Material: 6061-T6 Aluminum  
Total Price: \$6,827.25

Quantity	Unit Price	Total Price
20	\$341.36	\$6,827.25

Shipping To: 53705

Order Summary

**Total Price: \$6,827.25**

Part 6 is the 3D Model. Please Contact a Maple Plain, MN 55359 United States. [View our 3D CAD files & 2D Drawings](#)

©2023 Protolabs. All rights reserved. [Privacy Policy](#) [Terms of Service](#)

[Download](#)

**Quote\_8771-341.pdf (254 kB)**

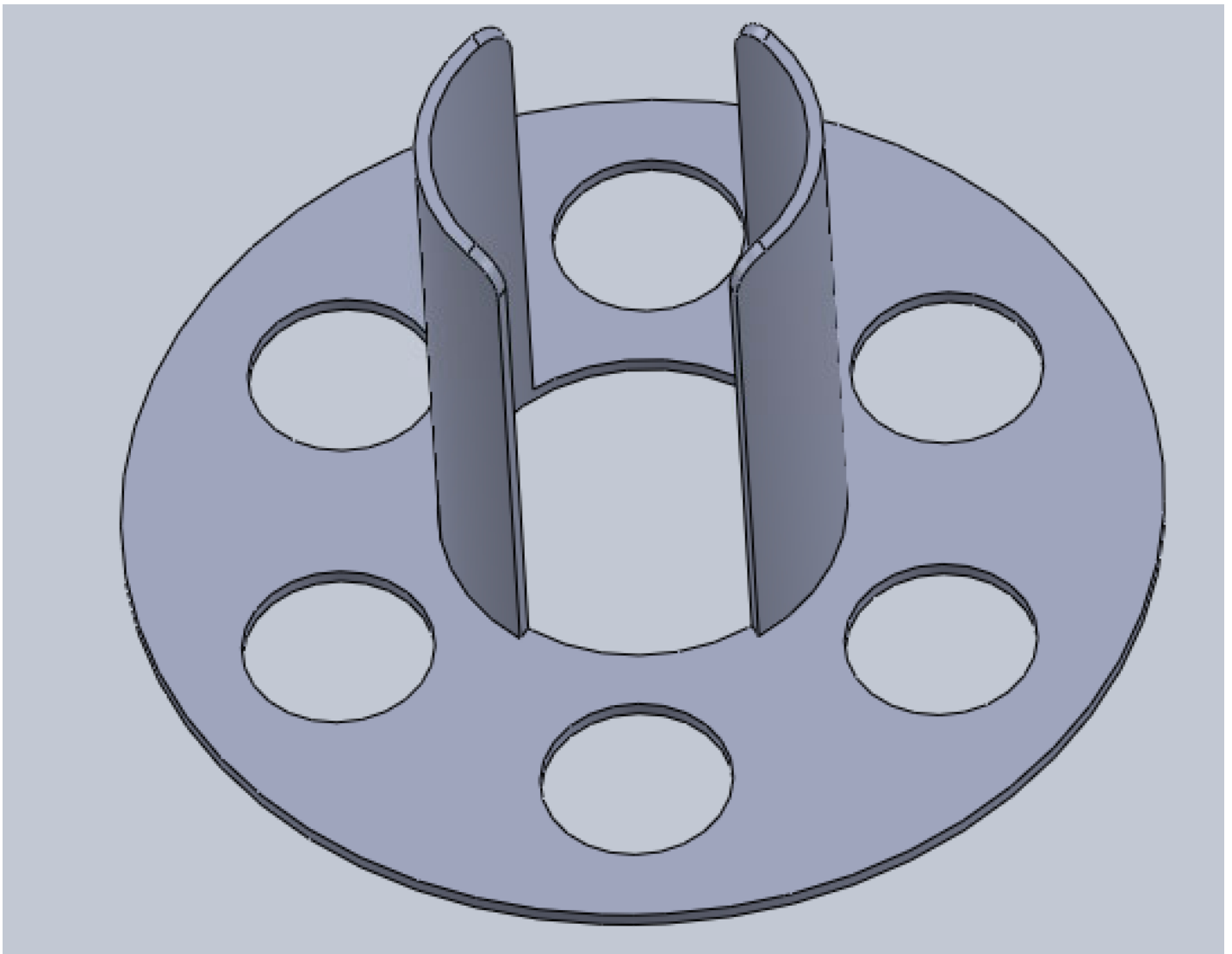
**Title:** Stand

**Date:** 3/7/23

**Content by:** Ben Smith

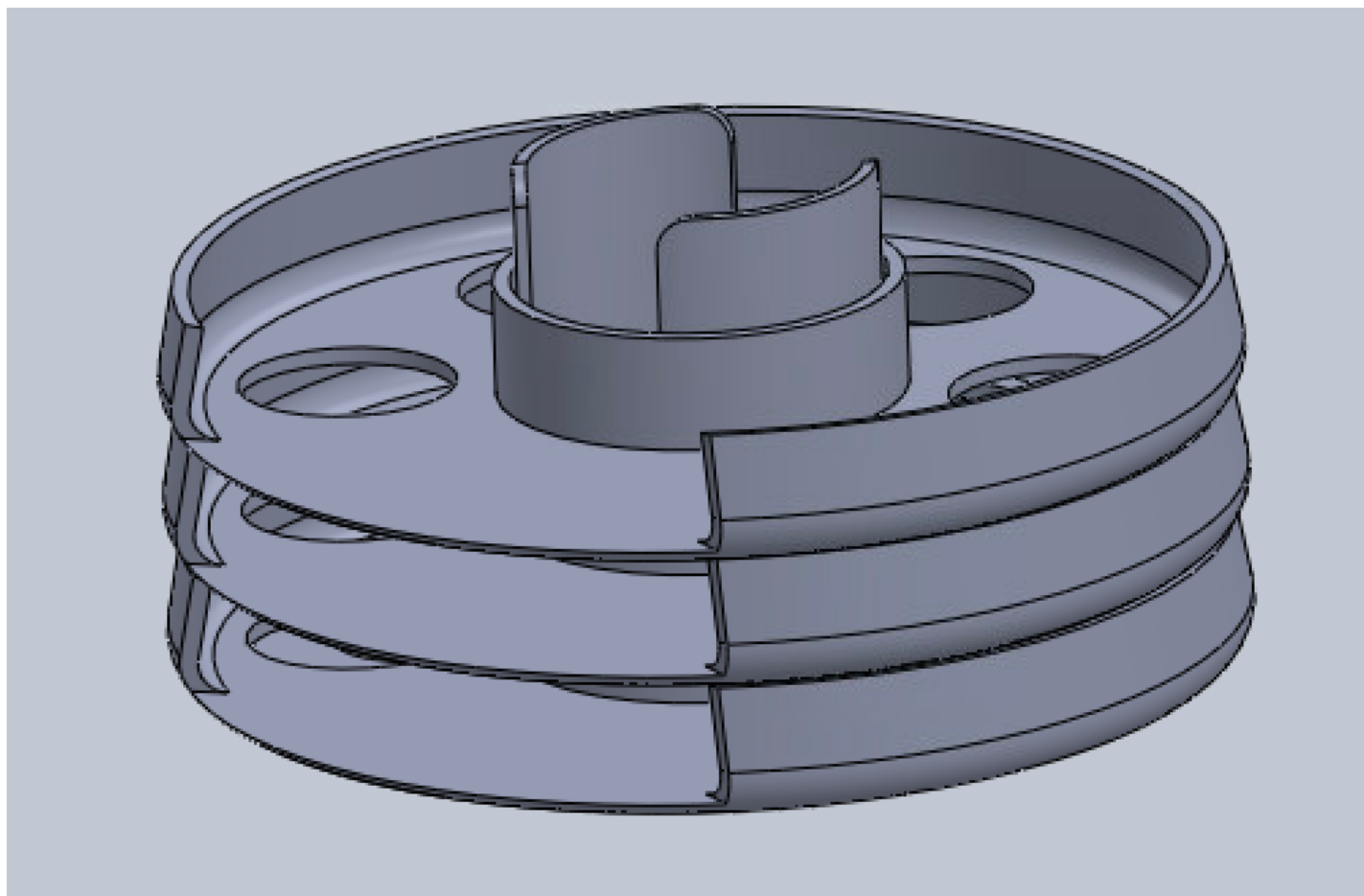
**Goals:** Update the stand to be compatible with the updated wheel designs

**Content:**



**Figure 1:** Updated stand with a larger chimney diameter to fit the wheels tighter

- The stand was updated to fit the diameter of the middle hole in the wheels
- The stand can now comfortably fit three wheels stacked on top of each other without too much excess chimney and without the wheels being loose



**Figure 2:** The stand with three wheels stacked on top

- Notice the comfortable fit between the wheels and the stand

**Conclusions/action items:**

The stand is now much more compatible with the wheel designs.

LILY GALLAGHER - Feb 14, 2023, 12:23 PM CST

John Puccinelli - Nov 03, 2014, 3:20 PM CST

**Title:** ASME - AMERICAN SOCIETY OF MECHANICAL ENGINEERS**Date:** 02/05/2023**Content by:** Lily Gallagher**Present:** Lily Gallagher**Goals:** To brainstorm different possible journals that we can submit our paper to**Content:**

- 36 JOURNALS TO CHOOSE FROM:

Journal of Medical Devices

**Purpose**

The *Journal of Medical Devices* presents papers on medical devices that improve diagnostic, interventional and therapeutic treatments focusing on applied research and the development of new medical devices or instrumentation. It provides special coverage of novel devices that **allow new surgical strategies**, new methods of drug delivery, or **possible reductions in the complexity, cost, or adverse results of health care**. The Design Innovation category features papers focusing on novel devices, including papers with limited clinical or engineering results. The Medical Device News section provides coverage of advances, trends, and events.

**Scope:** Orthopedic, cardiovascular, rehabilitation, neurological, urologic and other medical devices; Bio heat transfer devices; Medical sensors and actuators; Medical instrumentation; Image guided interventions and treatments; **Endoscopic, laparoscopic, and catheter devices**; Minimally invasive devices; Diagnostic devices; Tissue engineered devices; Drug delivery systems; Medical robotics; **Medical device design processes**; Medical device manufacturing processes; **Human factors as related to medical devices**; Computational methods for analyzing the performance of medical devices; Virtual prototyping of medical devices

**Frequency:** Quarterly

Types of papers:

## 1. Research Paper

Full-length, original research document that reports results of major and archival value to the specific community of engineers that comprise the journal audience. Recommended Length: 12,000 words. Beyond this amount, a mandatory excess-page charge may be assessed.

## 2. Design Innovation Paper

Represents scholarly innovation in design that has technological implications. The archival value of such papers is in the innovation part of a design and not necessarily in the theory. This type of paper is intended for outstanding work in mechanical design that is concept oriented and does not necessarily require detailed theoretical or experimental development and analysis, but does have archival value in design practice, as well as potential technological implications. Recommended Length: 7000 words.

**Basic Guidelines...****Title**

The title of the paper should be concise and definitive. This will increase the discoverability of your work and support SEO (search engine optimization).

**Author Names and Affiliations**

ASME's policy is all contributors who have participated significantly in the technical aspects of a paper be recognized as co-authors or cited in the acknowledgments. This list serves as a declaration that each individual has made a substantive and material contribution to the development and composition of the paper. The corresponding author(s) must be identified and contact information included. Adding or removing an author after submission requires a written statement from all of the authors.

**Abstract**

An abstract (250 words maximum) should give a clear indication of the objective, scope, and results so that readers may determine whether the full text will be of particular interest to them.

**Body of Paper**

The text should be organized into logical parts or sections with headings and subheadings throughout to divide the subject matter into logical parts and to emphasize the major elements. The purpose of the paper should be stated at the beginning, followed by a description of the problem, the means of solution, and any other information necessary to properly qualify the results presented and the conclusions. Results should be presented in an orderly form, followed by the author's conclusions.

**Equations**

Equations should be numbered consecutively beginning with (1) to the end of the paper, including any appendices. The number should be enclosed in parentheses and set flush right in the column on the same line as the equation. This number should be used when referring to equations within the text. Equations should be referenced within the text as “Eq. (x).” When the reference to an equation begins a sentence, it should be spelled out, e.g., “Equation (x).” Acknowledgments Acknowledgments may be made to individuals or institutions not mentioned elsewhere in the work who have made an important contribution.

**Funder Information**

The name and grant number for each funding source will be included in a separate section of your paper. During the submission of your final files for publication you will be asked to supply this information.

**Nomenclature**

Nomenclature should follow customary usage. For reference, consult American National Standards Institute (ANSI) recommendations. The nomenclature list should be in alphabetical order (capital letters first, followed by lowercase letters), followed by any Greek symbols, with subscripts and superscripts last, identified with headings. Appendices/Supplemental Material ASME currently supports only supplemental material that is integral to the understanding and comprehension of the archival version of a Research Paper accepted for publication. If an author has supplemental material that they would like to submit for inclusion, they must receive pre-approval at the time of submission from the Editor and include it at the end of the main paper. ASME is currently working on a solution for supporting non-integral supplementary material (e.g., datasets, etc).

**References**

Within the text, references should be cited in numerical order according to their order of appearance. The numbered reference citation within text should be enclosed in brackets. ASME primarily uses The Chicago Manual of Style for reference format. ASME does not allow references to Wikipedia.

**Figures and Tables**

All figures (graphs, line drawings, photographs, etc.) should be numbered consecutively and have a caption consisting of the figure number and a brief title or description of the figure. This number should be used when referring to the figure in text. ASME accepts .tif or .eps file formats for figures. All tables should be numbered consecutively and have a caption consisting of the table number and a brief title. This number should be used when referring to the table in the text. Table references should be included within the text in numerical order according to their order of appearance.

<https://asmedigitalcollection.asme.org/medicaldevices/pages/about>

**Conclusions/action items:**

**Title:** BMJ Innovations

**Date:** 02/05/2023

**Content by:** Lily Gallagher

**Present:** Lily Gallagher

**Goals:** To brainstorm different possible journals that we can submit our paper to

**Content:**

**Purpose:** BMJ Innovations is a peer reviewed online journal focused on emerging digital health, medical devices, process and system innovations. The journal champions high-quality original research, early-stage innovation reports, and systemic and narrative reviews.

BMJ is a Plan S Journal..

**What is Plan S? (and what does it mean for me as an author?)**

= Plan S is an initiative to drive wider adoption of open access publishing that was launched in 2018 by cOAlition S, an international consortium of organizations who fund or carry out research. The first and main objective was to require that, from 2021, publicly-funded research must only be published in journals or on platforms on an open access basis without embargo.

There are three routes for authors to be compliant with Plan S and BMJ supports all three routes:

- **Publish in open access journals or platforms** – A third of our journals are fully open access. In this model, authors pay an Article Processing Charge (APC) levied upon acceptance to make the article immediately available on publication. cOAlition S funders will continue to financially support APCs in open access journals.
- **Publish open access in a subscription journal under a transformative arrangement** – Either publish in one of the 36 BMJ journals which have now received TJ status from cOAlition S or under your institution's 'Publish and Read' agreement with BMJ, where one exists.
- **Publish in subscription journals AND make the article available in an open access repository**, but cOAlition S funders will not cover any open access charges involved.

We publish only about 7% of the 7000-8000 articles we receive each year (and just 4% of the ~4,000 research articles)

Conclusion/Action Items:

<https://innovations.bmj.com/>

Title: Journal of Biomedical Engineering and Medical Devices

Date: 02/06/2023

Content by: Lily Gallagher

Present: Lily Gallagher

Goals: To brainstorm different possible journals that we can submit our paper to

Content:

The Journal of Biomedical Engineering and Medical Devices is an academic journal providing an opportunity to researchers and scientists to explore the advanced and latest research developments in the field of Biomedical Engineering and related disciplines. The Journal is of highest standards in terms of quality. The Journal sought to publish articles related to Bioinstrumentation, Biomaterials, Nano materials for biomedical engineering and devices. Biomechanics, Cellular tissue and genetic engineering, Medical electronics, Clinical engineering, Medical imaging, Orthopedic surgery, Rehabilitation engineering, Systems physiology and many more. The Journal of Biomedical Engineering and Medical Devices is a scholarly Open Access journal and aims to publish the most complete and reliable source of information on the advanced and very latest research topics.

Article Categories

- Original Articles: reports of data from original research.
- Reviews: comprehensive, authoritative, descriptions of any subject within the scope of the journal. These articles are usually written by experts in the field who have been invited by the Editorial Board.
- Case reports: reports of clinical cases that can be educational, describe a diagnostic or therapeutic dilemma, suggest an association or present an important adverse reaction. Authors should clearly describe the clinical relevance or implications of the case. All case report articles should indicate that informed consent to publish the information has been granted from the patients or their guardians.
- Commentaries: short, focused, opinion articles on any subject within the scope of the journal. These articles are usually related to contemporary issues, such as recent research findings, and are often written by opinion leaders.
- Methodology articles: present a new experimental method, test or procedure. The method described may be new, or may offer a better version of an existing method.
- Letter to the Editor: these can take three forms: a substantial re-analysis of a previously published article; a substantial response to such a re-analysis from the authors of the original publication; or an article that may not cover 'standard research' but that may be relevant to readers.

Here are the files required for submission :

- Title page  
Formats: DOC  
Must be a separate file, not embedded in the main manuscript.
- Main manuscript  
Format: DOC  
Tables less than 2 pages each (about 90 rows) should be included at the end of the manuscript.
- Figures  
Formats: PPT, DOC, PDF  
All figures must be sent together as one separate file, not embedded in the main manuscript.
- Cover letter  
Formats: DOC  
Must be a separate file, not embedded in the main manuscript.

The title page should:

- provide the title of the article
- list the full names, institutional addresses and email addresses for all authors

- indicate the corresponding author

#### Acknowledgments, Sources of Funding, and Disclosures

- **Acknowledgments:** The acknowledgments section lists each individual's substantive contributions. Authors should obtain written, signed permission from all individuals listed in the 'Acknowledgments' section of the manuscript, because readers may infer their endorsement of data and conclusions. These permissions must be provided to the Editorial Office.
- **Sources of Funding:** Authors must list all sources of research support relevant to the manuscript. All grant funding agency abbreviations or acronyms should be completely spelled out.
- **Conflict of Interest:** Authors must state any disclosures in the cover letter when submitting a manuscript. If there is no conflict of interest, please state "Conflict of Interest: None to report." Conflicts of interest pertain to relationships with pharmaceutical companies, biomedical device manufacturers or other corporations whose products or services are related to the subject matter of the article. Such relationships include, but are not limited to, employment by an industrial concern, ownership of stock, membership on a standing advisory council or committee, membership of a board of directors, or a public association with the company or its products. Other areas of real or perceived conflict of interest could include receiving honoraria or consulting fees or receiving grants or funds from such corporations or individuals representing such corporations. The corresponding author should collect Conflict of Interest information from all co-authors before submitting a manuscript.

#### Tables and Figures

Each table should be numbered and cited in sequence using Arabic numerals (i.e., Table 1, 2, 3, etc.). Titles for tables should appear above the table and be no longer than 15 words. They should be pasted at the end of the document text file, in A4 Portrait or Landscape format. These will be typeset and displayed as such in the final, published form of the article. Tables should be formatted using the 'Table object' in a word processing program to ensure that columns of data remain aligned when the file is sent electronically for review. Tables should not be embedded as figures or spreadsheet files. Larger datasets or tables too wide for a Landscape page can be uploaded separately, as additional files. Additional files will not be displayed in the final, laid-out PDF of the article, but a link will be provided to the files as supplied by the author.

Figures should be provided in a separate single .DOC, .PDF or .PPT file, with a resolution of at least 300 dpi and not be embedded in the main manuscript file. If a figure consists of separate parts, please submit a single, composite illustration page that includes all parts of the figure. There is no charge for the use of color figures. The figure legends should be included in the main manuscript text file at the end of the document, rather than as part of the figure file. For each figure, the following information should be provided: Figure numbers in sequence, using Arabic numerals, a title of 15 words maximum and a detailed legend of up to 300 words. Please note that it is the responsibility of the author(s) to obtain permission from the copyright holder(s) to reproduce figures or tables that have previously been published elsewhere.

#### References

All references, including links, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, and should be formatted in the [National Library of Medicine style](#). Each reference must have an individual reference number. Please avoid excessive referencing. Only articles, datasets and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited. The author is responsible for obtaining permission to quote personal communications and unpublished data from cited colleagues. Journal abbreviations should follow Index Medicus/MEDLINE.

Citations in the reference list should include all named authors, up to the first 6, before adding 'et al.'. Any in press articles cited within the references and necessary for the reviewers' assessment of the manuscript should be made available if requested by the editorial office.

#### Style and Language

Longdom Publishing S.L. only accepts manuscripts written in English. Spelling should be either U.S. English or British English, but not a mixture. Longdom Publishing S.L. will not edit submitted manuscripts for style or language; thus, reviewers may advise rejection of a manuscript due to grammatical errors. Authors are advised to write clearly and simply, and to have their article checked by colleagues before submission. In-house copyediting will be minimal. Non-native speakers of English may choose to make use of our copyediting services. Abbreviations should be used as sparingly as possible and should be defined when first used.

In addition,

- Please use double-line spacing.
- Use justified margins, without hyphenating words at line breaks.
- Use hard returns only to end headings and paragraphs, not to rearrange lines.
- Capitalize only the first word and proper nouns in the title.
- Number all pages.
- Use the correct reference format.
- Format the text in a single column.



- Greek and other special characters may be included. If you are unable to reproduce a particular character, please type out the name of the symbol in full. Please ensure that all special characters are embedded in the text; otherwise, they will be lost during PDF conversion.
- SI units should be used throughout ('liter' and 'molar' are permitted).

#### Word count

For Original Articles, Methodology Articles and Reviews, there is no explicit limit on the length of papers submitted, but authors are encouraged to be concise. Commentaries and Case Reports should be between 800 and 1,500 words. Letters to the Editor should be between 1,000 and 3,000 words. There is also no restriction on the number of figures, tables, additional files or references that can be included. Figures and tables should be numbered in the order in which they are referenced in the text. Authors should include all relevant supporting data with each article.

The abstract of Original and Methodology Articles should not exceed 250 words and must be structured into Background, Methods, Results and Conclusions. For Reviews, please provide an unstructured, single paragraph summary of no more than 350 words, of the major points raised. For Commentaries and Case Reports, please provide a short, unstructured, single paragraph summary of no more than 150 words. For Letters to the Editor, please provide a short, unstructured, single paragraph summary of no more than 250 words.

Please minimize the use of abbreviations and do not cite references in the abstract. Please list your trial registration number after the abstract, if applicable.

Add a list of 3 to 10 keywords below the abstract.

The Accession Numbers of nucleic acid, protein sequences or atomic coordinates cited in the manuscript should be provided in square brackets and include the corresponding database name.

#### Initial Review Process

Submitted manuscripts will be evaluated initially by the editor-in-chief and an associate editor. A rapid, initial decision regarding whether to have a manuscript formally reviewed by two or more reviewers with appropriate expertise, or rejected without a formal review will be determined based on the quality, scientific rigor and data presentation/analysis of the manuscript. It is anticipated that approximately 70% of the submitted manuscripts will undergo formal review and 30% will be rejected without evaluation by external reviewers.

<https://www.longdom.org/authors-reviewers-editors.html>

Title: Research in Engineering Design

Date: 02/06/2023

Content by: Lily Gallagher

Present: Lily Gallagher

Goals: To brainstorm different possible journals that we can submit our paper to

Content:

Research in Engineering Design is an international journal that publishes research papers on design theory and methodology in all fields of engineering, focusing on mechanical, civil, architectural, and manufacturing engineering. The journal is designed for professionals in academia, industry, and government interested in research issues relevant to design practice. Representative topics include functional representation, feature-based design, shape grammars, process design, redesign, product data base models, and empirical studies. The journal also publishes state-of-the-art review articles.

- Publishes research papers on design theory and methodology in engineering.
- Emphasizes the underlying principles of engineering design and research results that are of interest to multiple engineering domains.
- Examines theories of design, foundations of design environments, representations and languages, models of design processes, and integration of design and manufacturing.
- Focuses on mechanical, civil, architectural, and manufacturing engineering.

Submission Guidelines...

Title Page

## Title Page

Please make sure your title page contains the following information.

Title

The title should be concise and informative.

Author information

- 
- The name(s) of the author(s)
- The affiliation(s) of the author(s), i.e. institution, (department), city, (state), country
- A clear indication and an active e-mail address of the corresponding author
- If available, the 16-digit [ORCID](#) of the author(s)

If address information is provided with the affiliation(s) it will also be published.

For authors that are (temporarily) unaffiliated we will only capture their city and country of residence, not their e-mail address unless specifically requested.

## Abstract

Please provide an abstract of 150 to 250 words. The abstract should not contain any undefined abbreviations or unspecified references.

For life science journals only (when applicable)

- 
- Trial registration number and date of registration for prospectively registered trials
- Trial registration number and date of registration, followed by “retrospectively registered”, for retrospectively registered trials

## Keywords

Please provide 4 to 6 keywords which can be used for indexing purposes.

## Statements and Declarations

The following statements should be included under the heading "Statements and Declarations" for inclusion in the published paper. Please note that submissions that do not include relevant declarations will be returned as incomplete.

- 
- Competing Interests: Authors are required to disclose financial or non-financial interests that are directly or indirectly related to the work submitted for publication. Please refer to “Competing Interests and Funding” below for more information on how to complete this section.

Please see the relevant sections in the submission guidelines for further information as well as various examples of wording. Please revise/customize the sample statements according to your own needs.

## Text

### Text Formatting

Manuscripts should be submitted in Word.

- 
- Use a normal, plain font (e.g., 10-point Times Roman) for text.
- Use italics for emphasis.
- Use the automatic page numbering function to number the pages.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.
- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Manuscripts with mathematical content can also be submitted in LaTeX. We recommend using [Springer Nature’s LaTeX template](#).

### Headings

Please use the decimal system of headings with no more than three levels.

### Abbreviations

Abbreviations should be defined at first mention and used consistently thereafter.

## Footnotes

Footnotes can be used to give additional information, which may include the citation of a reference included in the reference list. They should not consist solely of a reference citation, and they should never include the bibliographic details of a reference. They should also not contain any figures or tables.

Footnotes to the text are numbered consecutively; those to tables should be indicated by superscript lower-case letters (or asterisks for significance values and other statistical data). Footnotes to the title or the authors of the article are not given reference symbols.

Always use footnotes instead of endnotes.

## Acknowledgments

Acknowledgments of people, grants, funds, etc. should be placed in a separate section on the title page. The names of funding organizations should be written in full.

<https://www.springer.com/journal/163/how-to-publish-with-us#Fees%20and%20Funding>

LILY GALLAGHER - Feb 06, 2023, 2:11 PM CST



[Download](#)

ASME\_GUIDE.pdf (4.39 MB) ASME Author Guide



**Title:** Medical Device Packaging Validation and ISO 11607

**Date:** 02/12/23

**Content by:** Lily Gallagher

**Present:** Lily Gallagher

**Goals:** To gain a better understanding about medical device packaging standards

**Content:**

Medical device, pharmaceutical, and biotech companies must follow stringent medical device packaging validation of their device for an FDA or EU submission

The International Organization of Standardization (ISO) established 11607 for device manufacturers to demonstrate the potency of their sterile barrier packaging.

- The sterile barrier packaging must prove resilient enough to withstand various tests:
  - Environmental, distribution, and accelerated aging
  - Package strength and integrity testing.
    - ensures the package will not only survive its testing challenges but continue to maintain a sterile barrier.
- A medical package testing company can perform this testing in a controlled environment

## What is ISO 11607-1? - Sterilization of a product in its final container

ISO 11607-1 outlines requirements for materials, sterile barrier systems, and packaging systems of devices that must maintain sterility until point of use. Requirements and tests cover:

- **Materials**
  - Polycarbonates(PC)
    - high impact and thermal resistance.
    - good toughness, UV protection, durability, and electrical and optical properties.
  - Polypropylene(PP)
    - polypropylene-produced medical plastic parts can undergo extreme steam sterilization and maintain decent durability after processing.
  - Polyethylene(PE)
    - high resistance to impact and chemical and low moisture absorption
    - biologically inert and does not retain harmful organisms.
  - **Biocompatibility**
    - compatibility of medical plastic polymers with the body tissues without adverse effects.
    - materials must not release toxins or produce immunological or allergic reactions on exposure to body fluids.
    - As such, they do not interact with the body system due to their chemical and biological inertness.
  - **Sterilization**

- The property describes the ability of medical plastic materials to undergo sterilization processes.
- For example, the medical plastic part produced must resist potential damages when exposed to sterilization methods such as gamma and UV radiations, autoclave steam, dry heat sterilizers, and liquid chemicals.

Below are some other essential properties of medical plastic polymers:

- Good Mechanical Properties (abrasion resistance, impact strength)
- Thermal Stability
- Good Optical Properties or Clarity
- Non-permeability
- Chemical Resistance
- Good Flame Retardation
- Low Water Absorption
- Gamma and UV radiations
- Autoclave Steam
  - Kills spores at high temperatures utilizing water and steam
  - Less time and temperature (121 degrees celsius for 10-30 minutes)
- Dry heat sterilizers
  - No water involved
  - Kills spores at 160 degrees celsius for 1 hour
- Liquid chemicals
  - EO Sterilization
    - Liquid solutions (As EO is highly soluble, it will be dissolved rather than sterilize).
    - Protein type material (degradation)
    - Products placed in non-breathable packaging
      - EO packaging must be able to intake and outtake gas. Thus, a breathable packaging material must be used.
    - **Caution must be taken when using EO with the following items:**
      - Electronic devices, batteries, and powder (as these items may create an explosion risk)
      - Vacuum-sensitive products (as EO cycles require vacuum environment)
      - Mated surfaces (stopcocks, three-way valves).
      - Coatings applied to solid bleached sulphate, SBS, materials (as these coatings can drastically affect porosity and dwell time required in the EO sterilization cycle).
- **Preformed sterile barrier systems / Sterile barrier systems**
  - Seal integrity testing identifies any leaks around the seal area of your packaging system.
  - Seal integrity testing is followed by seal strength testing to evaluate the mechanical strength of your packaging system and the force needed to separate and open the seal.
- **Packaging systems**

## What is ISO 11607-2?

ISO 11607-2 outlines validation requirements for forming, sealing, and assembly processes. They are crucial to ensure that sterile barrier system integrity can be maintained until opened by the users of sterile medical devices.

## What do medical device companies need to know for package testing?

- Package system performance testing / Distribution simulation
- Stability testing / Shelf-life study
- Package system integrity testing

You should also be aware that testing can include:

- Visual inspection test
  - No visible tears or holes
- Peel strength test
  - Force it takes to peel back packaging
- Burst test
  - Pressure testing
- Dye penetration test
  - is widely used to detect surface breaking flaws.
  - low cost
- Creep test
  - Stress relaxation test
  - Amount of deformation experienced over a certain amount of time
- Bubble emission test
  - Submerging the package into water and then to ensure there are no leaks

## Writing a testing protocol

The testing protocol should describe:

- What will be tested
- What type of testing will be performed
- Acceptance criteria for each test
- Standards each test will be run to

Conclusions/action items:

Share information with the team and begin to further research materials, sterilization methods and package that would work for us.

<https://waykenrm.com/blogs/medical-plastic-material/>

<https://iso-inc.com/news/medical-device-packaging-validation-and-iso-11607/#:~:text=The%20International%20Organization%20of%20Standardization,%2C%20distribution%2C%20and%20accelerated%20aging.>



## Guidewire packaging

LILY GALLAGHER - Mar 21, 2023, 11:51 AM CDT

**Title:** Guidewire Labeling Requirement Guidance

**Date:** March 6, 2023

**Content by:** Lily Gallagher

**Present:** Lily Gallagher

**Goals:** To gain a better understanding of the labeling for our guidewire

**Content:**

PreMarket Submission Recommendations...

### Device Description:

- description of technological characteristics
- identification of configurations and models
- listing of materials
- identification of coatings
- description of joints
- images or engineering drawings.

### Predictive comparison:

-Manufacturers must compare their new device to a similar legally marketed predicate device to support its substantial equivalence

1. show how your device is similar to, and different from, the predicate.
2. Side by side comparisons, whenever possible, are desirable

Description	Your Device	Predicate Device (Kxxxxxx)
Indications for Use		
Wire Diameter		
Device Length		
Tip Length		
Tip Type and Shape		
Tip Flexibility		
Wire Material		
Coating(s) Material, Length and Location		
Tip Material		
Accessories		
Packaging Configuration		
Sterilization Method		
Shelf Life		

### Biocompatibility:



## Significance

- Guidewires contain patient-contacting materials, which, when used for their intended purpose, (i.e., limited direct contact with circulating blood), may induce a harmful biological response.

Recommendation:

- You should determine the biocompatibility of all patient-contacting materials present in your device.
- If your device is identical in composition and processing methods to guidewires with a history of successful use, you may reference previous testing experience or the literature

## Labeling:

### 1. Device Description

- Identify important components
- Identify important functions (ie: length and guidewires that )

### 2. Indications for Use Statement

- How device should be used

### 3. Contraindications

- We recommend including the following warnings, as applicable, in the instructions for use.

- Identify hazards or risks (Stand not on a flat surface)

### 4. Warnings

- A warning against reuse or re-sterilization of the device, which could affect non metallic components, such as “This device is intended for single use. Do not reuse or re-sterilize.”
- A warning statement about the unestablished safety and effectiveness of a reprocessed device intended for multiple uses. For example, “The safety and effectiveness of this device has not been established after being reprocessed for multiple uses.”
- A warning statement regarding the indications for which the device has been confirmed to perform as intended, such as the following: “The safety and effectiveness of the device has not been established or is unknown in vascular regions other than those specifically indicated.” For example, if a specific guidewire is only indicated for peripheral vascular use based on the information provided in the 510(k) submission, the device should include a warning that the safety and effectiveness of the device has not been established in the coronary vasculature or neurovasculature.

- Warning to not use without re-sterilize, that device is intended as single use

### 5. Directions for Use

We recommend that you provide specific directions for use of the guidewire.

-Explain how to stack the wheel on the stand, how to pull guidewire/wheel out

Conclusions/action items:

Present this notebook to the team and decide if we want to move forward with developing labelling for our guidewire

*Coronary/Neurology Recommendations*  
*Draft – Not for Implementation*

**Coronary, Peripheral, and  
Neurovascular Guidewires –  
Performance Tests and  
Recommended Labeling**

---

**Draft Guidance for Industry and  
Food and Drug Administration Staff**

**DRAFT GUIDANCE**

**This guidance document is being distributed for comment purposes only.**


**Document issued on June 15, 2018.**

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.fda.gov/oc/submitting-comments>. Submit written comments to Dockets Management Staff (HFA-105), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact:

- Interventional Cardiology Devices Branch (ICDB/DCD) at (301) 796-6329
- Neurointerventional Devices Branch (NIDB/DNPMDB) at (301) 796-2823
- Peripheral Interventional Device Branch (PIDB/DCD) at (301) 796-2520

**When final, this guidance will supersede "Coronary and Cardiovascular Guidewire Guidance" issued January 1995.**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health

[Download](#)

**Guidewire\_Packaging\_Labeling\_Guidance.pdf (471 kB)**

**Title:** Guidewire packaging

**Date:** March 6, 2023

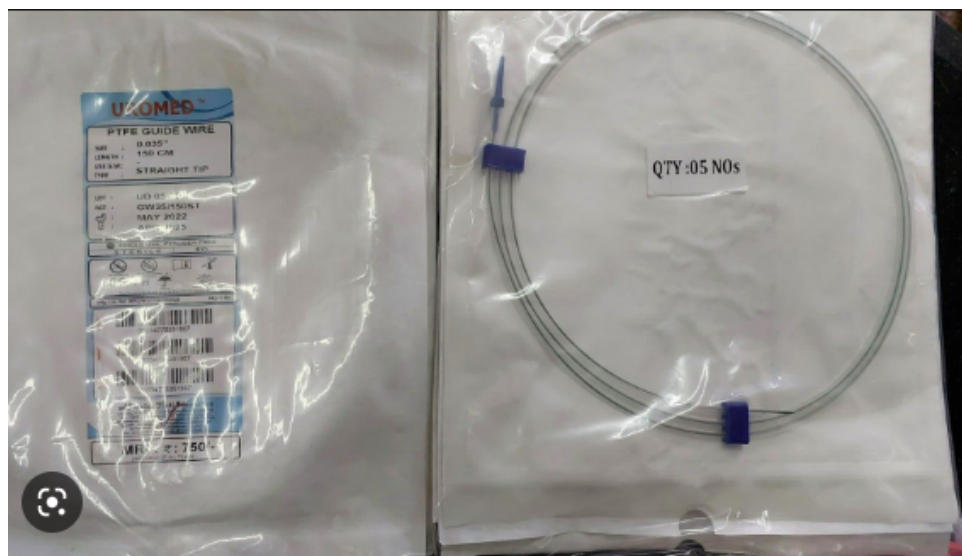
**Content by:** Lily Gallagher

**Present:** Lily Gallagher

**Goals:** To gain a better understanding of how guidewires are currently packaged in case we want to prepackage guidewires in our device

**Content:**



**Conclusion/action:**

Guidewires must be encapsulated by a material to ensure no kinking or movement

**Packaging a guidewire with our wheel would not work unless we reach out to a company that will essentially place on the bottom two designs into the wheel.**

**Title:** SolidWorks Drawings for Spring 2023

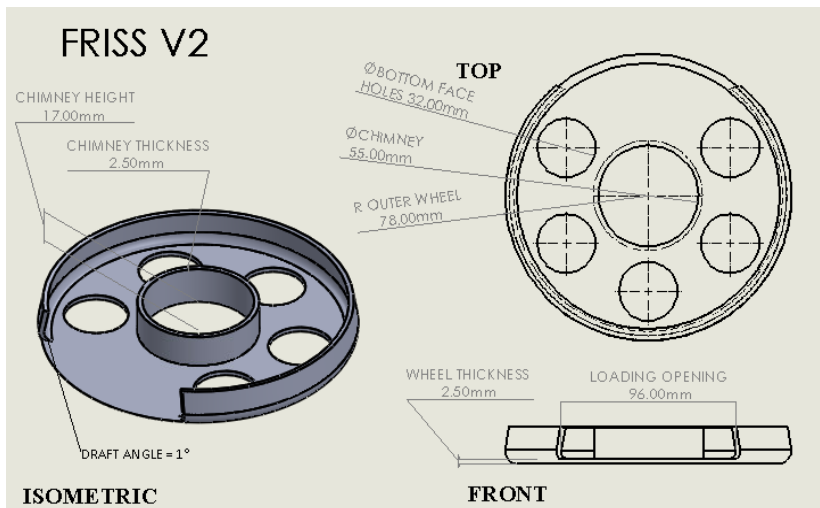
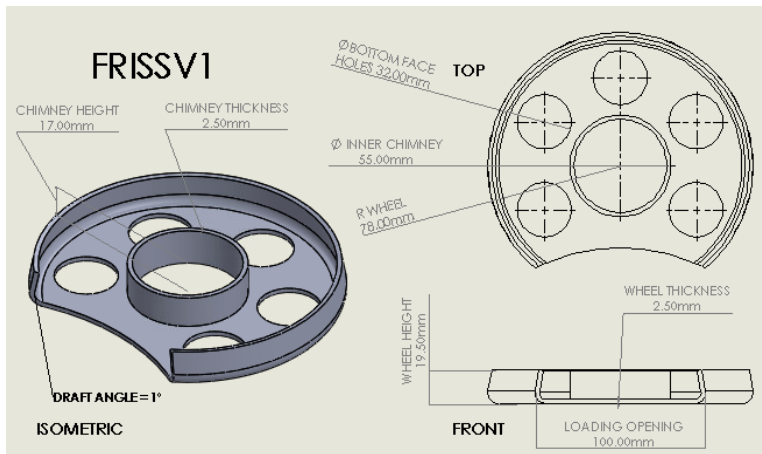
**Date:** 02MAY2023

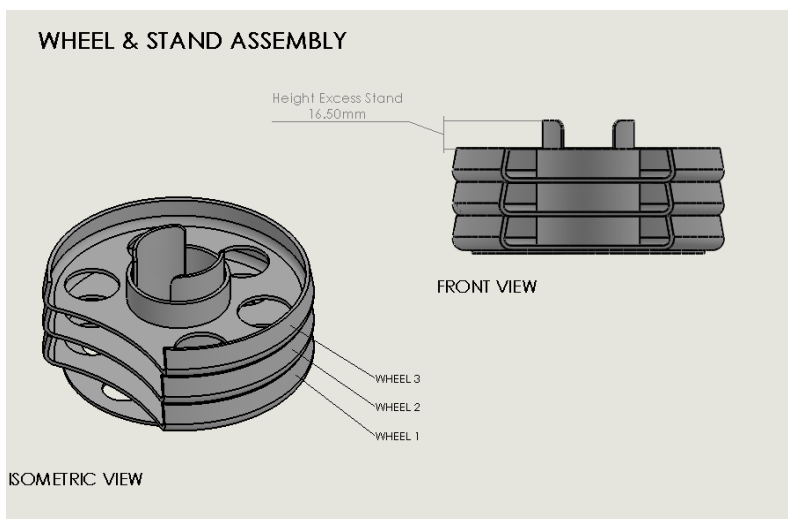
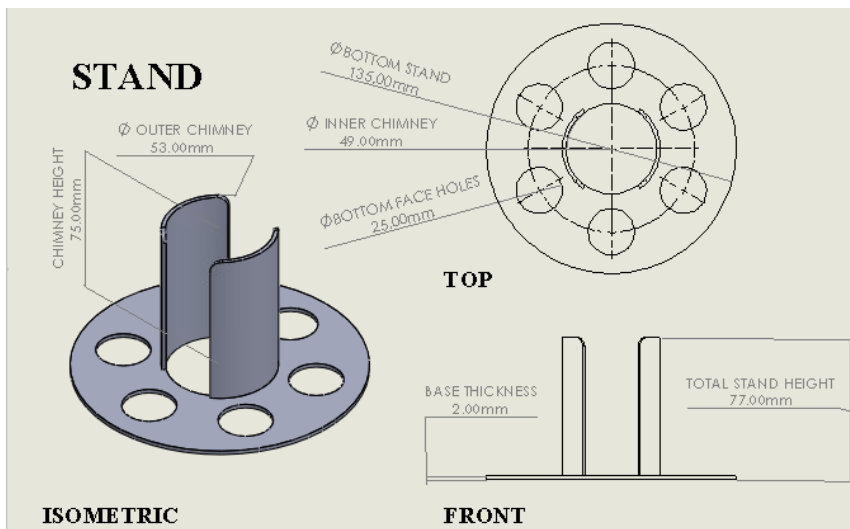
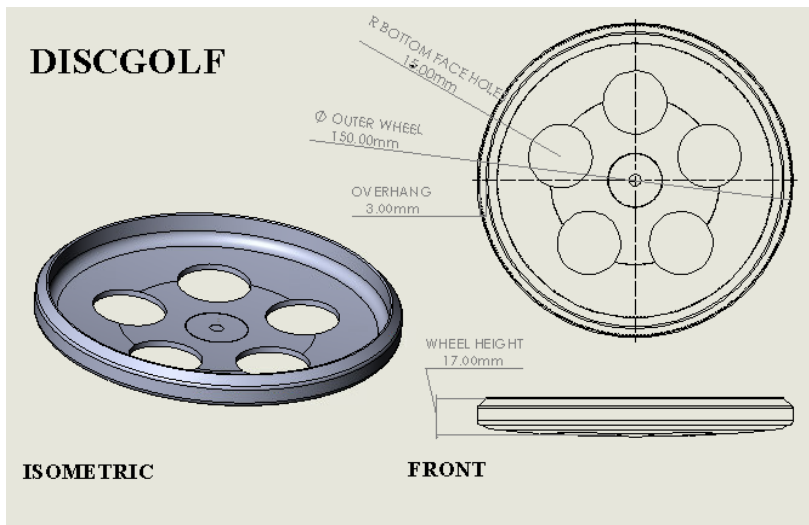
**Content by:** Lily Gallagher

**Present:** Lily Gallagher

**Goals:** To create dimensioned solidworks drawings for final deliverables

**Content:**





Conclusions/action items:

Add to Final Journal



## 2023/03/20 Warf Patent Process

---

ADDISON DUPIES - Apr 03, 2023, 10:28 PM CDT

**Title:** WARF Patent Process

**Date:** 03/20/2023

**Content by:** Addie Dupies

**Goals:** Understand the patenting process with WARF

**Content:**

- Warf has a six step process to apply and file for a patent

1. Submit an innovation disclosure.

- This is a primary document used to initiate the WARF review process.
- It helps determine patentability and provides some of the technical information they need for drafting a patent application
- Can expect to hear from them in 1-3 business days after submitting the form.

2. Have a disclosure meeting.

- An informal, confidential meeting about the details and possible applications of the invention
- Expect to hear from WARF after a month -- the internal decision committee meets once a month

3. Decision committee makes a determination

- They try to make decisions quickly so that patenting doesn't interfere with a publication
- The decision is based on factors like patentability, market dynamics, licensing potential, public benefit, and whether WARF can add value.

4. Disclosure goes through an equity review

- The Office of the Vice Chancellor for Research and Graduate Education will perform an equity review to identify contracts or funding sources that may have intellectual property obligations.
- The university has its own IP properties

5. Innovators with accepted inventions will enter into a memorandum agreement with WARF.

- This agreement defines the legal relationship with us and WARF
- We agree in this document to assign ownership to WARF so we can work in partnership during the invention patenting and licensing process
- In return, WARF agrees to share royalty income with us

6. WARF applies for the patent.

- We will work with our seasoned intellectual property experts, most of whom are also registered patent agents, and patent attorneys to draft a patent application
- They move fast to get the application filed and once filed, the patent application is examined by the patent office, a process that can take years.

**Conclusion/Action Items:** Dr.Y has already been in contact with WARF but from what we understand there is not sufficient information for our WARF to apply for the patent yet.





## 2022/02/13 Examples of Packaging of OR Devices

---

ADDISON DUPIES - Feb 13, 2023, 1:25 PM CST

**Title:** Examples of Packaging of OR Devices

**Date:** 02/13/2023

**Content by:** Addie Dupies

**Goals:** Find examples of packaging for OR devices that follow ISO 11607

**Content:**

The most common packaging for medical devices that follow ISO standards for medical packaging and sterilization are:

1. Pouches: These are a low-cost packaging option that allows for massive volume and quick lead times, meaning they mostly remain relegated to commodity products (our product). They can be stacked, thrown, and flipped around without adding much risk to the budget or supply chain.
2. Bags: another low-cost platform that provides superior opening options compared to a basic tear pouch. Something as simple as a resealable opening, like a “ziplock” or mild adhesive, can add tremendous value to the end user.
3. Forming Films: Polyurethane films are used industry-wide to protect prosthetic implants, surgical screws, and other medical devices that need to be malleable and durable over the long term. Combined with breathability, flexibility, and durability, forming films have everything you need to keep your device safe and sterile at a relatively low cost. -- (this would be unlikely for our device)
4. Laminations: Laminations are composed of two or more individual films that are used within the structure of a medical pouch or bag. Each film adds an extra layer of protection, such as UV, moisture, or corrosion barriers, to name a few. (Also unlikely for our device)
5. Die Cut Lids: This platform's rigid structure, typically shaped as a tray, allows for a form that holds the device in place. “Clean peel” technologies than ensure a clean and particulate-free opening motion. This one-two punch makes die-cut lids a preferred package by nurses and surgical technicians due to their ease of use. (Could be used for our product)
6. Thermoform Trays: Thermoforming is an excellent protective and cost-effective packaging platform that can be forged inside state-of-the-art certified Class 8 cleanrooms with high-speed machinery. Many medical device designers choose thermoformed packaging due to it's high impact resistance, glass-clear transparency, and its wide range of design and barrier options. (Could be possible just very high cost)

**Conclusion/Action Items:** Pouches, Bags, and Thermoform Trays are the best options for our device. Pouches and bags are perfect for commodity devices like our devices.



## 2022/02/08 Packaging for Class I/Class II devices

ADDISON DUPIES - Feb 13, 2023, 1:10 PM CST

**Title:** Packaging of Class I/Class II Devices

**Date:** 02/08/2023

**Content by:** Addie Dupies

**Goals:** Research how Class I and Class II devices must be packaged for sterility in the OR

**Content:**

Medical Device Packaging Validation and ISO 11607

- Medical device, pharmaceutical, biotech companies must follow stringent medical device packaging validation processes to obtain what they need for an FDA or EU submission
- Sterilized medical devices cannot be introduced to the market until there is a validation report proving that they will remain sterilized in the packaging until opened for initial use
  - Important for our device as the guidewire will touch the device and could risk contamination if not sterile
- ISO 11607 is the standard that has manufacturers demonstrate the potency of the sterile barrier packaging
  - This sterile barrier packing must be resilient to withstand the following tests - Environmental, distribution, and accelerated aging
  - This testing can be performed in a controlled environment
  - Package strength and integrity testing ensures that the packing will not only withstand the environmental, distribution testing, and accelerated aging but will maintain a sterile barrier through any challenge it faces from production to use
- There are two parts to the ISO 11607 standard
- ISO 11607-1
  - This part outlines the requirements for materials, sterile barrier systems, and packing of devices that must maintain sterility until the point of use
    - Materials, preformed sterile barrier systems, packaging systems
  - Our project would need to consider the packaging and the materials of the package and device
- ISO 11607-2
  - This part outlines the validation requirements for forming, sealing, and assembly processes to make sure that the device is sterile until the package is opened
  - Our project would need to consider where the product is made and how it will remain sterile in the factory
- Testing protocol for the packing not just the device itself - required by a regulatory agency
  - Should include: what will be tested, what type of tests will be performed, the acceptance criteria, and what standards each test will apply to

<https://iso-inc.com/news/medical-device-packaging-validation-and-iso-11607/#:~:text=The%20International%20Organization%20of%20Standardization,%2C%20distribution%2C%20and%20accelerated%20aging.>

**Conclusion/Action Items:** When considering packaging for the device the team must follow the ISO 11607 standard. This will allow for a regulatory submission on the device after the project is completed. The device and packaging must both be tested to this standard.



## 2014/11/03-Entry guidelines

---

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity, subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

**Title:** Descriptive title (i.e. Client Meeting)

**Date:** 9/5/2016

**Content by:** The one person who wrote the content

**Present:** Names of those present if more than just you (not necessary for individual work)

**Goals:** Establish clear goals for all text entries (meetings, individual work, etc.).

**Content:**

Contains clear and organized notes (also includes any references used)

**Conclusions/action items:**

Recap only the most significant findings and/or action items resulting from the entry.



**Title:**

**Date:**

**Content by:**

**Present:**

**Goals:**

**Content:**

**Conclusions/action items:**



BME Design-Fall 2022 - TATUM RUBALD  
Complete Notebook

PDF Version generated by  
TATUM RUBALD  
on  
Jan 31, 2023 11:01 AM CST

Table of Contents

Project Information	2
Team/Project Information	2
Project Description	3
Team/Project	4
Client Meetings	4
09SEP22 Initial Client Meeting	4
10E Faculty Member Injection Meeting	5
19OCT22 Client Meeting Update	6
Client Meetings	7
Final Advice Meeting 16SEP22	7
Meeting - 09SEP22	8
1024 Meeting (Weekend Check)	9
Design Process	10
20SEP22 Project Timeline	10
02OCT22 Manufacturing Process Design Matrix	11
Product Design Review Meeting - 08 12OCT22	13
16OCT2222 Task Delegation Oct 16	16
3NOV22 Team Showcase	16
11 1622 Show and Tell	17
Materials and Expenses	19
Semester Expenses 12NOV22	19
Fabrication	21
Semester Prototype Design - 16 13NOV22	21
Testing and Results	22
POC/Cell	22
Testing Protocol - 1 28 22	22
Experimentation	24
Testing Results and Analysis - 12NOV22	24
Project Files	25
09SEP22 DMC 488 PDS	25
09E 400 Preliminary Report - 10 6 22	26
09E 400 Preliminary Presentation - 18 08 22	27
09E 400 Final Presentation - 18 12 22	28
09E 400 Final Report - 18 12 22	29
Tatum Rubald	30
Research Notes	30
Biology and Physiology	30
27SEP22 Injection Molding	30
27SEP22 Snap Cap	30
02NOV22 Examples of Injection-Molded Devices	31
17NOV22 Thermforming	36
10E 122 Addition of Research on Introduction Procedures	37
09NOV22 2VOC Feedback	38
Design Ideas	39
20SEP22 Design Musculoskeletal System	39
27SEP22 Design Variations	40

[Download](#)

2023\_01\_30\_notebook\_72278.pdf (23.2 MB)